

103
FOOD QUALITY PROTECTION ACT OF 1993

Y 4. AG 8/1:103-29

Food Quality Protection Act of 1993...

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BEFORE THE

SUBCOMMITTEE ON DEPARTMENT OPERATIONS
AND NUTRITION

OF THE

COMMITTEE ON AGRICULTURE
HOUSE OF REPRESENTATIVES

ONE HUNDRED THIRD CONGRESS

FIRST SESSION

ON

H.R. 1627

AUGUST 2, 1993

Serial No. 103-29

SUPERINTENDENT OF DOCUMENTS
HONORARY



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FOOD QUALITY PROTECTION ACT OF 1993

MONDAY, AUGUST 2, 1993

HOUSE OF REPRESENTATIVES,
SUBCOMMITTEE ON DEPARTMENT
OPERATIONS AND NUTRITION,
COMMITTEE ON AGRICULTURE,
Washington, DC.

The subcommittee met, pursuant to call, at 1:05 p.m., in room 1302, Longworth House Office Building, Hon. Charles W. Stenholm (chairman of the subcommittee) presiding.

Present: Representatives Sarpalius, Dooley, Inslee, Bishop, Volkmer, Holden, Smith of Oregon, Gunderson, Allard, Barrett, and Canady.

Also present: Representative Pat Roberts, ranking minority member of the committee.

Staff present: Joseph Muldoon, associate counsel; John E. Hogan, minority counsel; Dale Moore, minority legislative coordinator; Glenda L. Temple, clerk; Stan Ray, Rob Wight, James A. Davis, Curt Mann, and Pete Thomson.

OPENING STATEMENT OF HON. CHARLES W. STENHOLM, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF TEXAS

Mr. STENHOLM. The subcommittee will come to order.

This afternoon the Subcommittee on Department Operations and Nutrition will hear testimony regarding H.R. 1627, the Food Quality Protection Act, in our ongoing effort to hear and to help identify and address legitimate concerns relating to the registration and the use of pesticides.

This legislation, introduced by Representatives Lehman, Bliley, and Rowland, amends the Federal Insecticide, Fungicide, and Rodenticide Act, better known as FIFRA, and the Federal Food, Drug, and Cosmetic Act. It currently has over 100 cosponsors, many of whom are on this committee.

During this subcommittee's last pesticide hearing, I indicated my intent to hear this legislation and then to mark up before the August recess. After further consideration and consultation, I understand that the administration is working diligently and expeditiously toward a comprehensive proposal which they expect to have up to us in September. Wanting to have the full benefit of considering the administration's efforts before moving forward with this legislation, we no longer anticipate marking up a FIFRA bill before September.

However, we fully intend for this subcommittee, working with the full Agriculture Committee, the Energy and Commerce Sub-

committee on Health and the Environment and the administration, to draft responsible and equitable legislation in the coming months to address the concerns represented before us today in H.R. 1627, as well as some issues not addressed in this legislation.

Over the past few months, this subcommittee has worked to identify areas where policy decisions can be made to decrease unnecessary health risks to consumers and increase public confidence in the food production sector, while maintaining the abundance and variety of foods available.

I look forward to hearing how this legislation may or may not address these areas of concern. With that, I look forward to all of your testimony, and thank you for helping this subcommittee understand these very complex issues so that we can begin the work of making the necessary improvements in this legislation.

I recognize Mr. Smith.

[H.R. 1627 appears at the conclusion of the hearing.]

OPENING STATEMENT OF HON. ROBERT F. (BOB) SMITH, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF OREGON

Mr. SMITH of Oregon. Thank you, Mr. Chairman. Congratulations for starting on time without anybody here. Thank you very much.

Mr. ROBERTS. I beg your pardon.

Mr. SMITH of Oregon. I want to thank you for—except the ranking minority member, of course—I probably should yield to Mr. Roberts without saying anything.

Mr. Chairman, I am delighted that you have selected H.R. 1627 to begin our deliberations. There has been a great deal of work obviously gone into this bill in the past and I think we have a jump step on the issue using this as a base for amendment.

This is a very difficult issue and one which I have great confidence in your leadership that we will reauthorize FIFRA, and I look forward to working with you and listening to these issues. Thank you.

[The prepared statement of Mr. Smith follows:]

STATEMENT OF
ROBERT F. SMITH
BEFORE THE
DEPARTMENT OPERATIONS AND NUTRITION SUBCOMMITTEE
AUGUST 2, 1993

Mr. Chairman, I'd like to applaud your decision to hold this hearing today. H.R. 1627, the Food Quality Protection Act, represents a responsible and comprehensive start for addressing the current issues associated with sale and use of chemical pest controls.

The Administration has recently asserted that the Environmental Protection Agency, the Food and Drug Administration and the U.S. Department of Agriculture are now working together to reduce the use of pesticides in agriculture production.

If this means that the Administration is interested in bringing new and efficient pesticide tools into practice, then I look forward to working with them. However, if they intend to pull the rug out from under production agriculture, to deny them safe, reliable and effective products, without benefit of sound, scientific assessment, then I will have to oppose their policy.

While the EPA Administrator has been willing to offer broad brush discussion of this policy in numerous forums, I regret she was unable to be here today to share the Administration's thoughts on HR 1627, an established and well known legislative proposal.

HR 1627 enjoys over 100 cosponsors, from the House Committee on Agriculture, from the House Committee on Energy and Commerce and among the membership of the House. In addition, legislation enjoys widespread support from the agriculture and food processing community, with endorsements from over 230 organizations.

Production agriculture, from the Arkansas Blueberry Growers Association to the Yuma Mesa Fruit Growers Association, understands the need to improve the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) while providing a workable alternative to the Delaney Clause.

HR 1627 would provide the Environmental Protection Agency the regulatory authority needed to more quickly eliminate the use of pesticides under the cancellation process, and remove time consuming paperwork constraints that have in the past slowed EPA efforts to prohibit the use of pesticides in emergency situations.

The Delaney Clause, while well-intentioned 34 years ago, has become an anachronism that must be replaced by a sound standard of negligible risk. Based upon the recommendations of the a 1987 National Academy of Sciences report, Regulating Pesticides in Food: The Delaney Paradox, HR 1627 would

finally replace the inconsistent standards that now govern pesticide residues with a single modern standard applied uniformly to pesticide residues in all foods.

Though drafted prior to the completion of the National Academy of Sciences report, Pesticides in the Diets of Infants and Children, HR 1627 has provisions that respond to recommendations of the NAS. The legislation calls on the Environmental Protection Agency to take into account the sensitivities of population subgroups when defining the risk of tolerances for pesticide residues.

This Subcommittee has conducted a number of hearings this year on many aspects of our nation's pesticide regulation policy, and I believe we have built an excellent record on the matter. I believe it is important for us to review the Administration's pesticide policy, still in development, and I anticipate we will be able to do so shortly after the August recess.

Today's witnesses represent the broad range of individuals and organizations that have an interest in FIFRA reform generally and HR 1627 specifically. I look forward to hearing their testimony and the Subcommittee's questions about how to improve this legislation.

Mr. STENHOLM. Mr. Dooley.

Mr. DOOLEY. No statement at this time.

Mr. STENHOLM. Mr. Bishop.

Mr. BISHOP. Thank you very much, Mr. Chairman.

I just would like to congratulate the chairman for his leadership on the subcommittee, for seeing that this legislation is being brought to the forefront.

I would like to congratulate Mr. Lehman, Mr. Rowland, and Mr. Bliley for their interest in it, and I certainly look forward to working on it and seeing if we cannot resolve what is a complex issue in a way that is reasonable and beneficial to all concerned.

Mr. STENHOLM. Mr. Canady.

OPENING STATEMENT OF HON. CHARLES T. CANADY, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF FLORIDA

Mr. CANADY. Thank you, Mr. Chairman.

I join in thanking you for conducting this hearing today. This is a very important issue for us in Florida. Our agricultural industry, of course, is an important part of our whole economy in Florida, and the issue of pesticide use and legislation is one of the most important issues for those of us in Florida.

If we are going to continue to provide a safe, affordable, and abundant food supply for the American people, I am convinced that we have to look at some serious reforms. I appreciate your leadership in this area, and I look forward to hearing from our colleagues who are here as well as the other witnesses who will be testifying today. Thank you.

[The prepared statement of Mr. Canady follows:]

CHARLES T. CANADY
2TH DISTRICT FLORIDA

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DEPARTMENT OPERATIONS AND NUTRITION
FOREIGN AGRICULTURE AND HUNGER

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Congress of the United States
House of Representatives
Washington, DC 20515-0912

THE HONORABLE CHARLES T. CANADY
of Florida

before the
House Agriculture Subcommittee
of Department Operations and Nutrition

August 2, 1993

Thank you, Mr. Chairman. As this subcommittee begins the important process of reviewing the federal regulations by which pesticides and agriculture chemicals are registered and reregistered, I believe it is important to ensure that sound science is the foundation from which we work. America's farmers and consumers rely on the outcome of the actions we begin today.

We will hear over and over today how America has the highest safety standards and lowest food prices in the world. We must not compromise this reputation in our attempts to make changes to the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) and the Federal Food, Drug and Cosmetics Act (FFDCA).

Florida's \$6.3 billion agriculture industry is a prime example of the impact the current pesticide regulations have had on the agriculture industry. Because of its sub-tropical growing conditions, Florida's agriculture industry relies on up-to-date, effective agriculture chemicals and pesticides to battle the ever-increasing number of pests and infestations. Unfortunately, because of the recent Les v. Reilly court decision, and pressures to restrict and sometimes eliminate the use of pesticides and chemicals, coupled with the time needed to research, develop and register new active ingredients, Florida's agriculture industry has found that the list of available pesticides is rapidly diminishing.

In order to pass meaningful and practical pesticide legislation, we must address several areas where current policy is either antiquated or irrelevant. First, it is essential that any new legislation address the so-called "Delaney Clause." With the improvement of science since the implementation of Delaney in the 1950's, we are now able to detect the minutest degree of a potentially cancer causing residue in foods. Strict interpretation of the Delaney Clause, which calls for a "zero-risk" tolerance level, will lead to the banning of numerous chemicals and pesticides that are safe and effective.

Second, we must address the issue of "minor-use" pesticides. While Florida's agriculture industry is by no means "minor", it has been forced to bear the brunt of chemical cancellations -- not because of health concerns, but because of economic concerns. Increased maintenance and testing fees have played a major role in the loss of several thousand pesticide registrations. Many agriculture chemical producers have voluntarily dropped registrations because of these increased costs.

Third, we must address the cancellation process. Four years is an entirely too long a period of time for the removal of a harmful chemical from the market. The judicial appeals process has made a mockery of the system that is supposed to protect the American public.

Mr. Chairman, there are numerous other areas that must be addressed so that the outcome of our actions will allow America's farmers to continue their livelihood. Also, any legislation we pass must continue to ensure the American consumer that our food supply is safe, abundant and reasonably priced.

I look forward to hearing the testimony of our witnesses today, and in moving toward a successful resolution of the pesticide and chemical problems currently being faced by America's agriculture producers. Thank you.

Mr. STENHOLM. I know of no one who has worked harder, expressed more frustration, took more flak as a result of the inability, in the past, of this subcommittee and the House Agriculture Committee and the Congress to deal with this rather complex, often controversial, subject than the gentleman from Kansas, Mr. Roberts, who I recognize at this time, now the ranking minority member of the House Agriculture Committee.

OPENING STATEMENT OF HON. PAT ROBERTS, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF KANSAS

Mr. ROBERTS. I thank the chairman, and I thought he was describing himself in reference to the rope we have been trying to pull and ended up pushing in regard to food safety reform.

I would like to welcome everybody to the 13th annual FIFRA family picnic that we are having here in the subcommittee room. I was over in 1300, which is why I was late.

I thought you were ready to mark up, Mr. Chairman and Mr. Smith, but, obviously, that is not the case. We need either a bigger room, more seats or fewer people, and I apologize that we don't have that to the various players and also our partners in this effort.

I am going to read some of my prepared statement so we can set the tone of this, Mr. Chairman. I do so only out of seniority and frustration with this issue.

I want to thank you for this review of H.R. 1627, the Food Quality Protection Act, and I especially want to welcome our colleagues from Energy and Commerce, Mr. Bliley, Mr. Lehman, and Mr. Rowland, although I don't see Mr. Rowland here. Perhaps he will arrive a little later.

But Mr. Lehman and Mr. Bliley, thank you so much for your efforts and your leadership in this regard. It is much appreciated. You have been very diligent. You have been consistent. You have been working hard to work with members of this committee to resolve the inconsistencies and the regulatory problems that surround the laws that govern the pesticides and their use.

Mr. Chairman, the National Academy of Sciences recently released a report by the National Research Council entitled "Pesticides in the Diets of Infants and Children." The report effectively highlights the legislative and the administrative complexities that surround our efforts to ensure regulatory agencies have the common sense authority and flexibility necessary to achieve a science-based balance between the benefits pesticides actually provide to society and the potential risks their uses also pose.

The NAS report and various statements from the administration officials say we in the United States are not facing a food crisis—the food supply is safe. However, we all agree steps can be taken to improve the scope, the technology, and the methodology of the procedures used to analyze the benefits and the risks of pesticides.

At this subcommittee's last hearing, members of the NAS committee, who wrote the children's report, testified we should not approach FIFRA and FFDCA reforms with a clean sheet of paper. I certainly agree. Instead, we need to be reviewing those areas where EPA needs statutory changes or clarifications in its authority.

Further, we must make certain congressional efforts to streamline the pesticide approval and review process do not again lock science in place with policies that effectively prohibit regulatory agencies and the chemical industry from utilizing advancements in technology and analytical methodology. Farmers and the food processing industry have been seeking a rational way to resolve the Delaney paradox since it landed on the front burner with the Alar issue.

During the 101st Congress, following Alar's trial in the media courtroom, and its conviction based on rejected scientific data, I joined Chairman de la Garza, former USDA Secretary and ranking minority member of the House Ag Committee Ed Madigan, and also Congressman Stenholm, the subcommittee chairman, in the introduction of legislation aimed at fixing that paradox. And today we are reviewing the third generation of that effort, H.R. 1627, introduced by the gentlemen who will be testifying.

The bill, whose chief sponsors from the Energy and Commerce Committee have joined us today, I think really provides a rational and flexible foundation upon which we can improve our current food safety policies. I will not disagree with those who suggest that many issues besides the Delaney problem need to be considered if we are to try to move a comprehensive food safety bill through the Congress.

I think the rest of the statement can be included in the record, and, in the interest of time, I will yield back, but I do want to thank both gentlemen again for persevering on their fine efforts. I am looking forward to hearing the witnesses, and I want to thank you for your leadership, Mr. Stenholm, and also yours, Mr. Smith.

It is a difficult challenge. I hope someday—since I came to the Congress in 1980 to get wheat prices up and get the deficit down, and we surely made a mess of that, and got assigned to FIFRA—that we can get this animal out of the chute and ride it for 10 seconds and thereby get a trophy that we would all certainly agree would be worthwhile. I yield back.

[The prepared statement of Mr. Roberts follows:]

The Honorable Pat Roberts
Hearing Statement
Department Operations and Nutrition Subcommittee
August 2, 1993

Thank you, Mr. Chairman, for this review of H.R. 1627, "The Food Quality Protection Act." I want to welcome our colleagues from the Energy and Commerce Committee -- Mr. Bliley, Mr. Lehman and Mr. Rowland -- and commend them for their diligent, consistent efforts to work with members of this Committee to resolve the inconsistencies and regulatory problems surrounding the laws governing pesticide and their use.

As we all are aware, the National Academy of Sciences recently released a report by the National Research Council on "Pesticides in the Diets of Infants and Children." The report effectively highlights the legislative and administrative complexities surrounding our efforts to ensure regulatory agencies have the common sense authority and flexibility necessary to achieve a science-based balance between the benefits pesticides provide to society and the potential risks their use may pose.

The NAS report and various statements from Administration officials have indicated we in the United States are not facing a food crisis -- the food supply is safe. However, we all agree that steps can be taken to improve the scope, the technology, and methodology of the procedures used to analyze the benefits and risks of pesticides.

At this Subcommittee's last hearing, members of the NAS committee who wrote the children's report testified that we should not approach FIFRA and FFDCA reforms with a clean sheet of paper. I certainly agree. Instead, we need to be reviewing those areas where EPA needs statutory changes or clarifications in its authorities.

Roberts, 8-2-93, page two

Further, we must make certain that Congressional efforts to streamline the pesticide approval and review process do not again lock science in place with policies that effectively prohibit regulatory agencies and the chemical industry from utilizing advancements in technology and analytical methodology. Farmers and the food processing industry have been seeking a rational way to resolve the Delaney paradox since it landed on the front burner with the Alar issue.

During the 101st Congress, following Alar's trial in the media's courtroom, and its conviction based on rejected scientific data, I joined Chairman de la Garza, former USDA Secretary and ranking member of the House Ag Committee Ed Madigan, and Congressman Stenholm, in the introduction of legislation aimed at fixing the Delaney paradox. Today, we are reviewing the third generation of that effort, H.R. 1627.

The bill, whose chief sponsors from the Energy and Commerce Committee have joined us today, provides a rational, flexible foundation upon which we can improve our current food safety policies. I will not disagree with those who suggest that many issues besides the Delaney problem need to be considered if we are going to move a comprehensive food safety bill through Congress.

However, I want to assure everyone interested in a balanced, meaningful food safety reform package that while new pesticide-related issues constantly surface, I will be fighting to make certain that long-standing problems are not simply rolled to the side of the road in favor of the latest hot-button concern.

Roberts, 8-2-93, page three

This includes consideration of FIFRA reforms that are needed, and that have been debated many times over the past decade, that can help streamline the process of registering and regulating a pesticide. Issues such as preemption, cancellation, suspension, minor use, anti-microbials, a variety of FIFRA-related non-agricultural concerns, and a review of reregistration provisions and timetables.

All of this items, as well as Delaney, must be addressed and resolved in a manner that allows -- perhaps in some cases forces -- EPA to utilize its resources in the most efficient manner. I stand ready to work with the members of the Subcommittee and Full Committee to meet our responsibilities in forging a FIFRA reform package that recognizes the importance of providing agriculture and the public with the pest control tools necessary to protect their health and well-being.

Mr. STENHOLM. Well, the gentleman certainly got the down and up correct in his 12 years in the Congress.

Mr. Sarpalius.

Mr. SARPALIUS. No statement, Mr. Chairman.

Mr. STENHOLM. Mr. Barrett.

Mr. BARRETT. Just to thank you, Mr. Chairman, for holding this hearing, and especially with two of the original cosponsors of the bill, H.R. 1627, with us today. I look forward to the testimony and I think in the interest of time I would ask unanimous consent that my opening statement become a matter of record, and I look forward to working with you and Mr. Smith in the process. Thank you.

[The prepared statement of Mr. Barrett follows:]

REMARKS OF THE HONORABLE
BILL BARRETT
DEPARTMENT OPERATIONS
AND NUTRITION SUBC.
AUG. 2, 1993

Mr. Chairman, I want to thank you for holding this afternoon's hearing regarding HR 1627. It's so good to see Mr. Lehman, Bliley, and Roland the original sponsors of the bill with us today.

As we all know, pesticides are strictly regulated under (FIFRA) Federal Insecticide, Fungicide, and Rodenticide Act and (FFDCA) Federal Food, Drug, and Cosmetic Act. And, pesticides are vitally important to American production agriculture as they have enabled US farmers to produce the safest, most abundant, and affordable food supply in the world.

However, due to a court ruling and the help of numerous media reports, there is a desperate need to update our food safety legislation. Without reform, the availability of our food supply is in great jeopardy.

For these reasons, 108 Members of Congress, including myself have joined Mr. Lehman, Bliley, and Roland in reforming our food safety laws through HR 1627 which unties EPA's hands by giving them discretionary authority to set pesticide residue levels for food. This legislation would also cancel pesticide registration through informal rule-making, require uniform residue tolerances, and encourage harmonization of US tolerances with international limits.

As our witnesses can attest, modern science and technology has come a long way since the creation of the Delaney Clause in 1958. HR 1627 makes sure the best science is brought to bear on risk assessment procedures.

The nation's farmers and consumers cannot afford to lose 32 pesticides this year and another 32 next year. It's time to move on this legislation which is based on sound scientific principles to restore public confidence and secure this nation's food and fiber.

Mr. Chairman, I thank you for the opportunity to share my thoughts and I look forward to working with you and Mr. Smith during this process.

Thank You!

Mr. STENHOLM. Thank you.

Any prepared statements received from the members will be placed at this point in the record.

[The prepared statement of Mrs. Clayton follows:]

Congress of the United States
House of Representatives
Washington, DC 20515

STATEMENT OF REP. EVA M. CLAYTON
SUBCOMMITTEE ON DEPARTMENT OPERATIONS AND NUTRITION

AUGUST 2, 1993

Thank you, Mr. Chairman, for holding this hearing to review legislation which attempts to improve the current body of law relating to pesticides. I am aware of the degree at which emotions are stirred from the mere talk of changing the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the Federal Food, Drug, and Cosmetic Act. I believe that we are all hopeful that we can make future alterations which will improve the means by which pesticides are assessed by the Environmental Protection Agency in order to benefit agriculture and the public interest.

Although I have not completely familiarized myself with the Lehman-Bliley-Rowland bill, I do believe that it addresses some of the fundamental problems which exist in pesticide review and assessment. I am particularly concerned by the so-called "Delaney Paradox," a problem which has long plagued the agriculture community. While the stakes are high for the interested parties, the act of resolving this problem before the end of this Congress is of great necessity.

Mr. Chairman, I am grateful for your role in facilitating this process. The recent hearings you have held are testament to the commitment you have to resolving this very difficult policy matter. I am convinced that we can be responsible to the public interest and improve the pesticides regime which currently exists.

I would like to thank the many panelists for participating in this hearing—especially my distinguished colleagues, Mr. Lehman, Mr. Bliley, and Mr. Rowland. Your remarks are crucial to improving our understanding of this issue.

Thank you.

Mr. STENHOLM. We are now honored to hear from two of our colleagues from the Energy and Commerce Committee, the two of the three gentlemen whose names accompany the legislation we hear today—Dr. J. Roy Rowland will be joining us somewhat later. He has a bill on the floor at this time—but we welcome you here. We look forward to hearing from you at this time.

First, I will recognize the Honorable Richard H. Lehman from California.

STATEMENT OF HON. RICHARD H. LEHMAN, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF CALIFORNIA

Mr. LEHMAN. Thank you, very much, Mr. Chairman, and members of the subcommittee.

I want to thank you for taking this legislation under consideration. Mr. Chairman, you have given us cause for optimism that we can at last resolve the paradox of Delaney in the near future and get on with our business in this area.

I and Congressman Bliley and Dr. Rowland strongly believe the measure you are hearing today represents the best approach for needed reform of our food safety laws. We appreciate this opportunity to present the legislation and explain the merits of the approach.

While I understand that the Agriculture Committee has only jurisdiction over the part of the bill which deals with pesticide reform, we cannot forget that this issue is irreversibly linked to food safety reform. We cannot tell farmers a certain pesticide is safe to apply to crops but not safe enough if any of its residue is left on the product being sent to be processed.

The recent study by the National Academy of Sciences on pesticides and children has highlighted the need for our updated food safety legislation. While the United States has some of the highest safety standards and lowest food prices in the world, there certainly is always room for improvement. This study and a recent circuit court decision upholding the Delaney clause demonstrate how easily outdated our food safety standards can become.

As you know, a 1950's amendment to the 1938 Federal Food, Drug, and Cosmetic Act, known as the Delaney clause, allows certain pesticides to be used on raw foods but not on processed foods. In other words, what is safe for an apple is not safe for the apple sauce.

EPA, in its enforcement of these divergent standards, has flexibly interpreted the standard for processed foods to allow for a negligible risk rather than a zero risk to human health.

Due to modern science, even the minutest degree of a potentially cancer causing residue can now be detected in foods. If the strict interpretation of the Delaney clause's zero risk standard is applied, then many safe and effective pesticides which ensure a pest-free, harmless food supply would be prohibited.

Unfortunately, because the ninth circuit court has taken away EPA's discretion to use a negligible risk standard, this is exactly what is happening today. EPA has threatened to ban 35 invaluable, widely used pesticides that would leave a harmless but traceable amount of residue in processed foods. As a Representative from the San Joaquin Valley of California, arguably the richest

food production area in the country, I share the concern of the growers that the uncertainty created by these developments may severely alter the framework of American agriculture. The loss of useful pesticides will lead to a loss of valuable crops, many unique to California, and an increased dependence on imported products.

That is why I have joined with my colleagues, Mr. Bliley and Dr. Rowland, in introducing H.R. 1627, the Food Quality Protection Act of 1993. This will provide the certainty needed to ensure a safe food supply. While no one argues against safety or the need to protect our children or our environment, these interests are not exclusive of the benefits derived from pesticide use. The two, if adequately balanced, can serve to provide a high quality, low cost, dependable food supply which does not threaten consumer health.

Mr. Chairman, our bill has four key provisions which serve to update our current food safety laws. First and foremost, it provides for a negligible risk standard and allows EPA the flexibility to define it based on constantly improving science. Second, it continues to allow EPA to consider the benefits of pesticide use when weighing its decisions on how best to promote public health. Third, it sets a national standard which promotes interstate commerce; and fourth, it speeds up the removal of chemicals from the market which may prove unsafe.

I cannot overemphasize the importance of allowing EPA the discretion to define "negligible risk." Without it, we repeat the same mistake we made with the Delaney clause of locking in to current science. While this is outside of your jurisdiction, flexibility on the residue side of the equation is essential to protecting the registration and application of chemicals which prevent dry rot, worm, and pest infestations, fungi, and scarring.

Without the benefits that such chemicals provide, the food supply would be limited and costly, and consumers would have to depend on imported products for the fruits and vegetables which they currently take for granted. Foods which are edible, healthy, and nutritious would be readily available only to those who can best afford them.

One of my greatest concerns is the impact the Delaney clause may have on minor-use pesticides. Of all the pesticides used, about 15 percent are applied to fruits and vegetables. Already several minor-use pesticides have not been registered under the FIFRA law because the cost of developing the needed data is prohibited.

An overly stringent approach to food safety reform would serve as a disincentive to registration of these chemicals which, while limited in their application, are critical in their effect.

In your consideration of broader FIFRA reform, I hope you will include protection of minor uses in addition to other limited FIFRA reforms included in our bill. Most importantly, our bill eliminates the formal adjudicatory hearing requirement for cancellation of pesticide registrations. This should improve the timeframe for cancellation of unsafe pesticides by years.

In addition, our bill calls for EPA to reassess each tolerance in coordination with the reregistration of pesticides under FIFRA. The bill promotes the development of integrated pest management techniques, and improves USDA's data collection. While I understand

that the subcommittee may go further in modifying the FIFRA law, I believe that provisions of H.R. 1627 are an important beginning.

Again, I want to commend the members of the subcommittee for going forward on this package. What we are asking here for simply in this legislation is to let science rule the day, not hysteria, not political judgments based on unscientific evidence and considerations, but let the science decide. We are willing to do that, the people who grow the fruit and vegetables are willing to do that. The people who supply them directly to the public are willing to do as well. To do anything else, I think, would be a serious mistake.

I appreciate your consideration today and I certainly look forward to working closely with you, Mr. Chairman, and other members of the committee as we move this legislation forward. Thank you.

[The prepared statement of Mr. Lehman appears at the conclusion of the hearing.]

Mr. STENHOLM. Thank you.

Next we will hear from Mr. Tom Bliley, Member of Congress from the great State of Virginia. A surviving member of the infamous Bruce-Bliley bill of the 102d Congress.

STATEMENT OF HON. THOMAS J. BLILEY, JR., A REPRESENTATIVE IN CONGRESS FROM THE STATE OF VIRGINIA

Mr. BLILEY. Thank you, Mr. Chairman. I am pleased to join with my colleagues, Mr. Lehman and Dr. Rowland, today to discuss the Food Quality Protection Act of 1993. This legislation is a much needed measure to modernize the United States' antiquated food safety laws and to ensure the continued integrity of this country's food supply.

We Americans are blessed with the most reliable, most safe, most affordable food supply system in the world. Unfortunately, developments in science and technology have outpaced the laws governing our food supply resulting in some confusion with the public.

The legislation before us today will remove any suspicion about the integrity of our food supply by updating our food safety laws to reflect the state of modern science.

This legislation strikes a delicate balance. It recognizes the importance of preserving our ability to produce a safe and abundant food supply, but it does not compromise on safety. It insists that the evaluation of risk be based upon real world circumstances. It will ensure prompt regulatory action to protect the public health while at the same time ensuring that emotion does not win out over good science.

Mr. Chairman, I applaud yours and my friend Mr. Smith's leadership on this issue. The subcommittee's action sends a strong message that Congress will address this issue with common sense. The bill before you has the support of a majority of the members of the two committees of jurisdiction. This is the right track to take and, Mr. Chairman, let's get the train moving. Thank you very much.

Mr. STENHOLM. Perhaps a little bit of further edification for members of this subcommittee as well as those assembled concerning the jurisdiction question.

The Agriculture Committee has jurisdiction over FIFRA, which is basically the registering, use, canceling, and/or suspending of pes-

ticides, which makes up only a small portion of H.R. 1627. There are a number of issues under the jurisdiction of FIFRA, however, that are not addressed in H.R. 1627 and which, Mr. Lehman, you mentioned a couple in your opening remarks, including preemption, minor use, worker protection standards, applicator certification and training, and lower risk registration standards, to name just a few.

Separate legislation, under the Federal Food, Drug, and Cosmetic Act, guides the setting of maximum limits and tolerances of pesticide residues on raw commodities, processed foods, and animal feeds.

This subcommittee intends to work closely with the subcommittee of jurisdiction at Energy and Commerce as well as the administration to ensure that any bill ultimately moving forward is legislation that fits together and works together in a common sense and equitable manner while maintaining the jurisdictional boundaries of this and other subcommittees affected.

In that, I would say I have been very pleased with the stated intention of cooperation and the evidence thereof and the fact that our staffs are working together now. I have talked to Chairman Dingell and to Chairman Waxman, and I am happy to report that our staffs have begun the procedures, the necessary communications that will be necessary to carry this rather difficult and complex task we have before us to an eventual successful ending.

One of the things that we have going for us today that we have not in the previous 13 years is that almost all parties today accept the fact that the time has come to act. In fact, we can no longer afford to do nothing.

Whatever your perspective regarding the legislation happens to be, we must recognize that we can't let these issues go unaddressed without paying some very high prices, of which I am happy to say that so far the indication from most parties is a recognition of this fact, and that gives us some pause perhaps in what otherwise might be a more pessimistic attitude facing the beginnings of this process.

Mr. Smith, would you—I don't have any questions of either of you today. Mr. Rowland will join us sometime today for any opening remarks he would like to make.

My only question would be, of the statement that I just made, and you have already indicated your willingness, and I think since our two committees have the joint jurisdiction responsibility, the fact that the majority of the members of both committees support the legislation that you have put forward indicates that there is the kind of movement forward that you have expressed and we look forward to working with you.

Mr. Smith.

Mr. SMITH of Oregon. Thank you, Mr. Chairman. I just have one question.

Do you know of any food processor or any production agricultural organization that opposes this bill?

Mr. BLILEY. I don't know of any.

Mr. LEHMAN. I don't know of any either. There is a lot of diversity out there and there may be some changes some might want to see in some areas. Any time you put a big piece of legislation

like this together you will have to make some compromises, but I don't know of any.

I would, in 30 seconds, say in response to the chairman, I think everyone now recognizes the need to change the current law. There is general acceptance out there of the fact that Delaney does not work and it needs to be changed. The question is how is it going to be changed.

The approach we are offering for your consideration is one based on the best science available and on the continuing evolution of science and the application of it to the real world that we live in.

We are willing, the people we represent are willing to live with the results that that science gives us without having some arbitrary unscientific standard set up in law, which Delaney has. To just substitute Delaney for something equally as arbitrary and unscientific would simply be to make the same mistake again and we should not do that. I would really look forward to working with you. Thank you.

Mr. SMITH of Oregon. I wonder if you know of anybody or any organization who opposes the elimination of Delaney in favor of the negligible risk that you have proposed?

Mr. BLILEY. I don't know of any. I suppose there might be some out there, but I don't know who they are.

Mr. SMITH of Oregon. In that case, Mr. Chairman, I call for the question.

Mr. STENHOLM. Well, there might be one or two differences of opinion that we might better proceed.

Would any other member of the subcommittee like to ask a question?

Mr. Roberts.

Mr. ROBERTS. Yes, thank you, Mr. Chairman.

Tom, either you or Rick have any idea as to your subcommittee's schedule in progressing on food safety reform here on our particular subcommittee?

Mr. BLILEY. As far as I know, I have not heard anything from the chairman of the subcommittee as to when he might be willing to call the measure up for debate, even though, as we pointed out, a majority of the subcommittee are cosponsors, but maybe Rick has more information than I am privy to.

Mr. LEHMAN. I really don't. There is a rival bill over there in that committee offered by the chairman of the subcommittee.

Mr. ROBERTS. A rival bill?

Mr. LEHMAN. That bill, a somewhat different approach than ours, I understand will not be referred to this committee because it does not deal with the same areas.

But as Tom pointed out, we have a majority coauthoring our bill on both the subcommittee and the full Committee of Energy and Commerce. Maybe we will hear more testimony about this today, but I understand the administration may come out with something in September.

Mr. ROBERTS. That was my next question, and I will jump to that, along with certainly issuing a warm welcome to your cosponsor, Congressman Rowland.

What is your view of the administration's position policy in regard to food safety? Has that been issued in any kind of comprehensive way?

They have indicated a keen interest and have been willing to testify, and the EPA Administrator is very interested in this and it is a top priority, but do we have an administration policy on food safety?

Mr. ROWLAND. I have not heard of a definite policy, yet. I understand they are supportive of the National Academy of Sciences' study on making a determination about what levels of chemicals should be determined to be carcinogenic in individuals, but I do not know of any specific policy they have at this point.

Mr. ROBERTS. But you mentioned, Rick, that might be forthcoming in September?

Mr. LEHMAN. I have heard that. I don't know specifically what they are going to come out with. I am somewhat encouraged with their attitude, but I would hope they would adopt our approach, which is just clearly based on science rather than looking at the two possibilities out there in legislation, cutting the two in half, and coming down the middle somewhere, which would not be in the best interest of anyone here.

So I would hope they would move over to this approach, but just in the little conversations we have had, clearly, they recognize the Delaney clause cannot continue as it is and has to be changed.

Mr. STENHOLM. Would the gentleman yield?

Mr. ROBERTS. Yes, be happy to.

Mr. STENHOLM. The administration has indicated to me that they are working on this position at this very moment and that they intend to be ready to testify before this subcommittee towards mid-to late-September. And at that time we will have a hearing for purposes of hearing all administration witnesses concerning the bill before us, and then we will proceed to mark up. I will assume that the Energy and Commerce appropriate subcommittee will follow the same general timeframe. That is the assumption under which we operate today.

Mr. ROBERTS. I thank the Chair, and I yield back.

Mr. STENHOLM. Welcome, Dr. J. Roy Rowland, the third member of the Lehman-Bliley-Rowland team here today. We welcome you and any opening remarks you might like to make before we have any other questions.

STATEMENT OF HON. J. ROY ROWLAND, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF GEORGIA

Mr. ROWLAND. Mr. Chairman, I want to thank you and the subcommittee for the attention you have focused on this legislation and for what you are doing to move it forward. I think it is so very important we make a determination about what chemicals affect individuals in a scientific way, not just some arbitrary way. I appreciate the work that this subcommittee has done in moving this and focusing attention on this legislation.

I do have a statement, Mr. Chairman. I won't make this statement here, but I will ask unanimous consent, if you don't mind, if I can submit it for the record.

Mr. STENHOLM. Without objection and with much appreciation.

Mr. ROWLAND. Yes, I thought you would appreciate that, and I am sure that I agree with everything, with almost everything that my two colleagues have already said here today. But I do think it is so very important for us to make a scientific determination about how chemicals affect individuals. You know, there is a recent study that attention has been given to how children and infants are affected and I think our bill will help address that problem as well because there is a great deal that is not known about that.

So, Mr. Chairman, I won't make any additional statement at this time, but I would be receptive to any questions that you or members of the subcommittee may have.

[The prepared statement of Mr. Rowland appears at the conclusion of the hearing.]

Mr. STENHOLM. Any additional questions members of the subcommittee would like to make?

Mr. SMITH of Oregon. Mr. Chairman, just a comment.

Mr. STENHOLM. Mr. Smith.

Mr. SMITH of Oregon. Dr. Rowland, we had a chance to listen to the people who wrote the National Academy of Sciences' report indicating by a press release that there was some fear about children's consumption of foods. Listening to them, they rejected that point. They, like everyone else, agreed you can improve food safety, you can improve the weather in Hawaii, but they rejected the fact that food is not safe.

Food is safe, in their opinion. Food is safe for children in their opinion, and they were unanimous in that, and I thought it was revealing for them to come forward after some had interpreted their report as to pass a cloud on food safety, especially for children. So it was very informative to listen to them and be encouraged that our food is safe.

We can improve it, no question, but especially for children, it is safe.

Mr. ROWLAND. I will read just one paragraph from my statement since you have made that statement, and I go on to say, the U.S. food supply is the safest, most wholesome and most abundant food supply in the world. Today's foods are safe from pathogens, diseases, and parasites and are more nutritious than ever.

And I feel this way, and I think that is what these people were saying. I think what they were saying is that we need to look at this from a scientific basis to make the determination about how infants and children are affected by these agrochemicals that are used on the production of our food, and they were not saying the food supply us unsafe for infants and children, and you certainly make a very cogent point.

Mr. STENHOLM. Mr. Bishop.

Mr. BISHOP. Thank you, Mr. Chairman. I would just like to take this opportunity not to ask a question but to again commend my colleague from Georgia, Mr. Rowland, as I did in his absence, before he got here, in commending the other authors of this legislation for the fine work they have done.

I am especially proud that my colleague from Georgia is playing a part. Because during my campaign, knowing not as much about agricultural issues as I hope to know, the Delaney clause came up quite frequently in my travels. And for a colleague from Georgia to

be able to address this and to have the credibility as the only member of the medical profession in the Congress, I just want to commend him for that, and he adds a great deal of credibility to the effort of the other two colleagues of yours and of ours, and I want to say thank you and to commend you for it.

Mr. ROWLAND. Thank you, Mr. Bishop.

Mr. STENHOLM. We thank each of you for being here. We do look forward to working with you in the days and weeks ahead. Thank you very much.

Call panel 2. Ms. Doyle, Mr. Gardner, Ms. Duggan, and Mr. Bell.

We will ask all our witnesses in the remaining panels as well as members of this subcommittee now to abide with the 5-minute rule. Each of your entire statements will be made a part of the record, and we will look forward to your summaries thereof and then to the question and answer period.

First witness we will call, the Honorable Rebecca Doyle, director, Illinois Department of Agriculture, representing the National Association of State Departments of Agriculture and the Association of American Pesticide Control Officials.

STATEMENT OF REBECCA DOYLE, DIRECTOR, ILLINOIS DEPARTMENT OF AGRICULTURE, ON BEHALF OF THE NATIONAL ASSOCIATION OF STATE DEPARTMENTS OF AGRICULTURE AND THE ASSOCIATION OF AMERICAN PESTICIDE CONTROL OFFICIALS

Ms. DOYLE. Good afternoon. Thank you, Mr. Chairman, and members of the subcommittee.

I am Becky Doyle, director of the Illinois Department of Agriculture and neighbor and colleague of committee member, Mr. Ewing, and of the nonsurviving sponsor of H.R. 1627.

Mr. Chairman, before proceeding to the topic of today's hearing, allow me to thank the House of Representatives for passing legislation that could ultimately bring substantial and desperately needed relief to Midwestern farm communities affected by excessive rains and flooding.

Illinois farmers have lost an estimated 850,000 acres of crops. The damage to Illinois agriculture is quickly approaching \$600 million and may exceed that amount considerably before the flood of 1993 is behind us. So on behalf of the Illinois agricultural community, I thank all House Members who had the compassion, wisdom, and foresight to support flood relief legislation, which is truly in the best interest of the entire Nation.

Turning now to the subject of the hearing, it is a pleasure to appear before this subcommittee on behalf of the National Association of State Departments of Agriculture to discuss the matter of pesticide regulation. I will summarize my testimony and ask that my written remarks be placed in the record.

NASDA is a nonprofit association of public officials representing the departments of agriculture in 50 States and four territories. In most cases under a cooperative agreement with the Environmental Protection Agency, the State Departments of Agriculture serve as the lead State pesticide regulatory agency. Therefore, I bring a unique perspective on pesticide regulations and the reauthorization of FIFRA. In addition to NASDA, my testimony today represents

the position of the Association of American Pesticide Control Officials.

NASDA and AAPCO members represent the frontline pesticide regulators who must balance human health and environmental protection with farmers' and consumers' needs, and face both State and local anxiety over pesticide use and regulation.

American consumers can be confident that the U.S. food supply is safe from unreasonable risks presented by pesticide residues. Both NASDA and AAPCO believe H.R. 1627, the Food Quality Protection Act of 1993, will improve Federal regulation of pesticide use and establish national uniform tolerances for residues in food based upon a negligible risk standard, as recommended by the National Academy of Sciences.

Adoption of this legislation will allow the United States to continue to produce the safest, most economical, and most abundant food supply in the world. NASDA and AAPCO strongly support passage of H.R. 1627 and encourage the House Agriculture Committee to move quickly to favorably report the bill.

This legislation improves FIFRA significantly. H.R. 1627 would eliminate the current formal adjudicatory hearing requirement for cancellation of pesticide registrations. Removing harmful pesticides from the market takes significant time. The EPA may cancel a pesticide registration under FIFRA if information shows that the pesticide presents an unreasonable risk to human health or the environment. However, the cancellation process can be unnecessarily time-consuming and expensive and has rarely reduced controversy about either a pesticide's continued use or EPA's ability to regulate pesticides responsibly.

This bill would provide for scientific committee peer review of the evidence supporting proposed cancellation, precancellation notice to pesticide registrants, the U.S. Department of Health and Human Services, and USDA, advanced public notice and comment on proposed cancellation actions, FIFRA scientific advisory panel review of cancellation proposals, and the right to an informal cancellation hearing.

H.R. 1627 would allow EPA to issue emergency suspension orders before a proposed cancellation order has been issued provided the Administrator proceeds expeditiously with the cancellation proceeding. This procedural change will continue to ensure that if a pesticide should be suspended, EPA can do so expeditiously.

H.R. 1627 would direct USDA to collect pesticide use data of statewide or regional significance for all major crops and crops of dietary significance and to coordinate with EPA.

This pesticide use data collection is important, but only a beginning to the cooperation which is necessary. We strongly suggest that language be added which will require consultation between the Federal agencies and the State agencies which must implement the programs and policies.

H.R. 1627 is the only comprehensive pesticide regulation bill pending before the 103d Congress. It not only amends FIFRA but makes important and necessary changes to the Federal Food, Drug, and Cosmetic Act.

It would also replace the application of the Delaney clause with the single negligible risk standard made applicable to tolerances for pesticide residues and raw commodities and processed foods.

We, as an organization, also have some suggestions for additions to H.R. 1627, and those are set forth in our written testimony, so I will not go into them at this time. But we do thank you for the opportunity to testify today and would be glad to answer any questions at this time.

[The prepared statement of Ms. Doyle appears at the conclusion of the hearing.]

Mr. STENHOLM. The next witness, Mr. Sherwin Gardner, senior vice president for science and technology, Grocery Manufacturers of America.

STATEMENT OF SHERWIN GARDNER, SENIOR VICE PRESIDENT, SCIENCE AND TECHNOLOGY, GROCERY MANUFACTURERS OF AMERICA, INC.

Mr. GARDNER. Thank you, Mr. Chairman and members of the subcommittee. I represent the Grocery Manufacturers of America which is an 85-year-old national trade association comprised of over 130 companies which manufacture food and other products sold in retail stores throughout the United States.

Mr. Chairman, GMA recognizes and greatly appreciates your long and constructive efforts in seeking to bring about reform of this Nation's pesticide laws. GMA has reviewed with great interest the provisions of H.R. 1627 and we applaud the work undertaken by the bill's sponsors, Congressmen Lehman, Bliley, and Rowland, as well as the dozens of cosponsors of the proposed legislation.

This bill represents a marked improvement over a number of proposals for the regulation of food-use pesticides introduced in Congress during the last decade. GMA supports passage of this legislation.

Changes in science and technology since enactment of the Miller pesticide amendments in 1954 make it entirely appropriate to review and revise the act to ensure continuation of the high standard of safety and also to make the process of establishing residue tolerances more efficient and effective. Many of the advances in analytical chemistry and the science of quantitative risk assessment could not have been foreseen several decades ago.

Furthermore, last year's decision of the United States Court of Appeals for the ninth circuit in *Les v. Reilly*, invalidating the EPA's policy of disregarding de minimis risks under the Delaney clause, has complicated EPA's task of applying the statute in a rational and scientifically defensible fashion.

GMA believes that the Agency has ample authority under the existing statute to respond to the *Les* decision in a reasoned manner and to set tolerances to permit continued use of valuable pesticides that pose negligible risks. Nonetheless, legislative reforms would ensure that such cramped judicial interpretations of the law do not unnecessarily restrict EPA's regulatory options now or in the future.

The bill before you would make a much needed change in the act by establishing a negligible risk standard for pesticide residues in both processed and unprocessed foods. The National Academy of

Sciences recommended such a change in a 1987 report on that subject. Because these and other proposed revisions of current law would appropriately modernize regulation of food-use pesticides, GMA endorses H.R. 1627.

There are six specific elements of the bill which hold particular interest for us. First, the negligible risk standard, which would adopt the negligible risk standard as the basis for establishing safe pesticide residue levels in food. This standard in the bill also specifically addresses the concerns expressed in the recent NAS report on children's exposures to pesticide residues by mandating that EPA consider these and other sensitive population groups.

Tolerances for processed foods is also a very important element of this bill of interest to us. We agree that both processed and unprocessed foods should be subject to the same negligible risk standard. The flow through provision recognizes that pesticide residues normally decrease during processing and H.R. 1627 properly retains this provision.

National uniformity is the third of these six elements, and we applaud the provision of the bill precluding States from issuing different tolerances, warning label requirements, or other limitations on residues in food products and pesticides registered or reregistered after April 25, 1985.

We also strongly endorse the provisions for determining dietary exposure, treatment of products from the pipeline, and streamlining the cancellation suspension procedures when warranted.

In sum, Mr. Chairman, GMA supports H.R. 1627. This bill represents a balanced approach to recent difficulties encountered in EPA tolerance setting activities. We thank you for inviting GMA to participate in this hearing.

[The prepared statement of Mr. Gardner appears at the conclusion of the hearing.]

Mr. STENHOLM. Thank you.

Next Ms. Juanita Duggan, senior vice president, government affairs, National Food Processors Association.

STATEMENT OF JUANITA DUGGAN, SENIOR VICE PRESIDENT, GOVERNMENT AFFAIRS, NATIONAL FOOD PROCESSORS ASSOCIATION, ACCOMPANIED BY CLAUSEN ELY, LEGISLATIVE COUNSEL

Ms. DUGGAN. Thank you, Mr. Chairman. I am accompanied by our legal counsel, Clausen Ely.

We commend the chairman's leadership in holding a hearing on H.R. 1627, and I believe you have entered our full statement in the record.

Mr. STENHOLM. Yes.

Ms. DUGGAN. NFPA strongly supports H.R. 1627 as a balanced and comprehensive approach to the regulation of food-use pesticides. A fundamental underlying theme of the bill is to require EPA to collect and use the best available toxicological data and pesticide use and residue information in making tolerance determinations.

As the subcommittee is well aware, on June 29, 1993, NAS published a widely publicized report on Pesticides in the Diets of Infants and Children. We agree with the report that better data are

needed for regulatory decisions and that special emphasis should be placed on the evaluation of potential risks to infants and children. H.R. 1627 would promote both of these goals by requiring EPA to obtain and use actual pesticide use and residue data and by directing EPA to take into account all relevant factors, including the dietary exposure levels of major population subgroups of food consumers, such as infants and children, in making negligible risk determinations.

NFPA believes statutory changes are the best long-term mechanism for rationalizing and improving tolerance regulation. It is important to recognize, however, EPA has sufficient authority under current law to avoid unwarranted revocation of pesticide tolerances. The committee is well aware of the ninth circuit court of appeals ruling in *Les v. Reilly*.

EPA argued the ninth circuit decision may force the agency to revoke tolerances for a large number of valuable pesticides. We submit, however, that EPA has full authority to regulate pesticide tolerances in a manner that would minimize the impact of the Delaney clause decision. In fact, there is strong evidence that is what Congress intended.

The potential devastating loss of important agricultural use pesticides we face today is not a result of the *Les v. Reilly* decision but of EPA's so-called coordination policy. The coordination policy is an EPA invention that should be repudiated.

This policy requires issuance of a section 409 food additive tolerance whenever there is a possibility that a pesticide residue might concentrate in a processed food and mandates that, if a section 409 tolerance cannot be issued, that EPA must also revoke the section 408 tolerance and cancel the underlying pesticide registration.

In September 1992, NFPA, the United Fresh Fruit and Vegetable Association, and other food groups, filed a petition urging EPA to rescind its coordination policy and no longer require separate, unnecessary 409 tolerances for pesticides in processed food.

The NFPA petition demonstrates that continuation of current EPA policy will require numerous costly tolerance revocation proceedings and will force the agency to cancel safe beneficial pesticides that pose trivial risks. These actions will reduce the availability and increase the cost to consumers of nutritious fruits and vegetables and grain products, at the very time that FDA and the medical community are recommending greater consumption of these foods to prevent disease.

There is no sound legal or public policy basis for EPA to continue its coordination policy, and EPA should not be permitted to use the policy to create an artificial pesticide crisis.

Before addressing the specific provisions of H.R. 1627, very briefly I would like to stress three important underlying points with regard to pesticide reform. First, NFPA strongly supports programs to develop efficacious alternatives to pesticides. Second, it is essential to recognize that pesticides provide vital benefits for American consumers and agriculture. And finally, any pesticide legislation must be judged in light of its impact on minor uses.

I will touch on the important provisions of H.R. 1627 that we support. NFPA supports amendments to streamline both the cancellation and suspension provisions of FIFRA to allow EPA to re-

move hazardous pesticides from the market without unreasonable delay.

We strongly support establishing a consistent negligible risk standard for raw and processed foods consistent with the National Academy of Sciences' 1987 recommendations. We believe this is essential to the rational regulation of pesticides.

We support provisions requiring EPA to calculate dietary exposure on the basis of the percent of raw agricultural commodities actually treated with a pesticide, and on the basis of the actual residue levels detected in treated commodities and the processed food produced from those commodities. This would help avoid exaggerated and unjustified exposure calculations and would assist in developing more realistic risk assessments.

The bill would make clear that EPA retains authority to establish a tolerance for a pesticide residue posing greater than a negligible risk if EPA determines that there are countervailing benefits. EPA would be directed to take into account health and consumer benefits, including the impact of the loss of a pesticide on the availability of an adequate, wholesome, and economical food supply in making tolerance decisions.

We strongly urge retention of the flow through provision of current law. Under the flow through provision, where a tolerance or an exemption is in effect for a pesticide chemical on raw agricultural commodity, a residue of that chemical in a processed food made from the raw agricultural commodity is considered safe as long as the level of the residue does not exceed the tolerance prescribed for the raw commodity.

NFPA also supports a strong national uniformity provision for pesticide tolerances that meet current data requirements; and the pipeline provision, which would allow for the orderly withdrawal of legally treated food with a pesticide when a tolerance is revoked; and last, but not least, in order to promote international harmonization of tolerances, we support the provision requiring EPA to take into account and justify any departure from recommended levels issued by Codex Alimentarius.

We commend the subcommittee for opening a dialogue on H.R. 1627 and we stand ready to work with the Congress to develop pesticide food safety legislation. Thank you.

[The prepared statement of Ms. Duggan appears at the conclusion of the hearing.]

Mr. STENHOLM. Thank you.

Next we will hear from Mr. Harry Bell, vice president of American Farm Bureau Federation, and president of South Carolina Farm Bureau.

STATEMENT OF HARRY S. BELL, VICE PRESIDENT, AMERICAN FARM BUREAU FEDERATION, AND PRESIDENT, SOUTH CAROLINA FARM BUREAU

Mr. BELL. Mr. Chairman, gentlemen of the subcommittee, I am Harry Bell. I am a farmer, president of the South Carolina Farm Bureau, and vice president of the American Farm Federation, and I will digress from my statement just a bit because I could not come before this subcommittee and not piggyback on the comments of the lady from Illinois about the flooding situation. We do appre-

ciate the drought being included in that legislation as well, one which we are suffering at this very moment.

But we appreciate the opportunity to address the important issues raised by H.R. 1627, the Food Quality Protection Act of 1993. The interest in modernizing our laws governing food safety is shared by farmers, ranchers, and all Americans. This important task ought to be guided by an understanding of two very important facts. First, scientists and experts in and out of Government have repeatedly stated our food supply is safe, that there is no ominous threat to public health, we do not need radical change.

Overcompensating for fears of pesticides is a risk in itself, a risk that might jeopardize an agricultural system that produces the safest, most abundant, and most affordable food supply in the world. We have the luxury of refining an already safe system, but we must avoid the temptation to change simply for the sake of change itself.

Our policy refinements, therefore, should be carefully calculated with undesired, unexpected results in mind. They should not be random shots in the dark. Second, pesticides remain an essential tool for the recommended economical food supply. At the risk of political incorrectness, they are the best technology currently available.

Agricultural production will, for the foreseeable future, continue to be dependent on the use of pesticides to protect our food supply from weeds, insects, and diseases. Although we should continually strive to improve pest control through new technology and cultural practices, such goals will only be realized in time and with an investment in research.

Farmers are changing the way we farm. We are switching to newer, more environmentally sound techniques, such as integrated pest management and biological controls. If you tell cotton growers how to control whiteflies without insecticides, they will do it; tell potato growers how to control late blight without fungicides, they will do it; tell apple growers how to control apple scab without fungicides, they will do it.

Policies based on the belief that simply canceling pesticides improves food safety ignores the real world damage that pests inflict on crops and ignores the changes in farming practices already underway. Good science shows that most pesticide cancellations have little effect on food safety but can have disastrous effects on farmers and consumers.

Under current regulations, farmers that grow so-called minor crops, a category that includes almost all fruits and vegetables, are losing the ability to combat pests because minor crops are grown only on a small percentage of farmland. The current regulations for pesticide registration are so burdensome, chemical companies cannot profit from minor crop pesticides and are simply discontinuing them.

Farm Bureau supports H.R. 1627 because it takes a comprehensive and a balanced approach to pesticide regulation. More specifically, we support the bill because it replaces the outdated Delaney clause with a single negligible risk standard for pesticide residues in both raw and processed foods. Strict enforcement of the Delaney

clause will not improve safety; in fact for some crops and pests, the Delaney standard leads to increased pesticide use.

By replacing Delaney with a flexible negligible risk standard and retaining benefits consideration, H.R. 1627 would achieve the desired goals of making a safe food system safer while minimizing disruptions to agriculture.

Other aspects of Farm Bureau's support for H.R. 1627 are detailed in our written statement. We appreciate your consideration, and I would be happy to respond to any questions.

[The prepared statement of Mr. Bell appears at the conclusion of the hearing.]

Mr. STENHOLM. Ms. Doyle and Mr. Bell, I will ask the first question in general perhaps to you, to share with this subcommittee some of the recent developments in pesticide regulations in your States, or in the areas in which you are familiar and in which you are testifying on behalf of NASDA, but some of what the current situation is with some of the current efforts under the present legislation.

Ms. DOYLE. During our legislative session just ended, we passed what was referred to as local preemption or a bill that would make the State pesticide law the law of the land rather than allowing local units of government to modify the pesticide laws for the State.

However, through that there is still a process for local hearings, for local units of government to apply for more stringent pesticide laws. But that is an issue that is not only very sensitive in Illinois, but also one that throughout the State is one that our organization, NASDA, and AAPCO are both working on to try to make more consistent pesticide and chemical laws across the United States and one that is very timely.

To the more general theme, though, I think that as the gentleman from the Farm Bureau said, farmers are searching for and the industry is searching for more environmentally sound ways of dealing with pests and health problems for their plants. I think that they are in the vanguard now of looking for those and trying to develop those. This legislation would go a long way toward supporting those efforts and recognizing the realities that farmers have to deal with.

Mr. BELL. Mr. Chairman, I would certainly endorse what the lady has said. In addition to that, we have provided each of you a copy of this material put together by the Minorcrop Farmers Alliance. There are some 13 crops listed in that material from South Carolina that are affected, some \$507 million, almost \$508 million, everything from peaches to truck crops.

Just as a personal example, whitefly in my cotton in Saluda, South Carolina, whitefly is something that is coming our way. It is certainly giving other farmers difficulty. We have had difficulty controlling that particular pest.

Mr. STENHOLM. I feel compelled to repeat a comment I made at our last hearing. Since you are from South Carolina, Mr. Bell, as difficult as it is for a Texan ever to admit any other State ever does anything first or better, we have yet to see provable evidence thereof, but some we have to accept.

As we have pursued the general subject before us today concerning food safety, whether we are talking FIFRA or whether we are

talking about our Food Safety Inspection Service, it is something that is absolutely critical to producers in America that we maintain the consumer confidence.

One of the frustrations that we have felt is that from time to time consumer confidence is attacked, sometimes with merit and sometimes with not so much merit. But the end result is always the same. That is, there is a price to be paid at both the producing and the consuming levels.

We have been pursuing the general thought and concept which we thought was something that was very new and original, and that is to begin involving the public health sector more in some of these debates and discussions, in the belief that this would be very productive to the question at hand.

We were reminded that South Carolina, in 1984, did just that, concerning a problem that you had in your peach crop at the time. You created the AgraMed system, which is apparently working very well and is something that we hope we can emulate in the other 49 States, because, as each of you have mentioned, the absolute necessity of laying the foundation for the subject at hand, based on science, you will always find scientists who will differ as to the conclusions of the science. So eventually you have to have some credible entity that will, in fact, certify as to the science at hand, whether or not it is credible, that will have some credibility with the American people.

That is where I commend the action of South Carolina. But to your credit and to—his name escapes me right now, but the Doctor from South Carolina.

Mr. BELL. Dr. Stan Shumer.

Mr. STENHOLM. That is correct. Thank you.

He pulled out a little book and began reading that it was not South Carolina in 1984, someone else had the original idea in 1825, that we ought to involve the public health sector in determining credibility of statements that are made or not made regarding the safety of our food supply.

This is a subject we intend to follow with a great amount of diligence. I know of no one who has greater credibility with every person in this room than your family doctor. That is why the presence of Dr. J. Roy Rowland in this effort, I think, is significant.

But more important than that, as we strive for some of the answers to some of the questions that are very illusive from time to time, we intend to pursue this thought and use the South Carolina, I will not say experiment, because it is much more than that, it is very successful today, and begin to build some credibility into the statements at hand.

Mr. Smith.

Mr. SMITH of Oregon. I have just one question.

There is obviously a great public stigma developed against chemical pesticides. Many, when you say "chemical" go bananas and many have come before this subcommittee recommending we take the biological approach. Is that a reasonable suggestion?

Do we have enough biological background to replace chemical pesticides?

Ms. DOYLE. I think there is a possibility to begin transitioning that way, but I think at this point, it would not be a case of being

able to do that in one growing season. That leads to one of my pet peeves, that we don't have enough money for research anymore, as I am sure members of your committee have heard before. But agricultural research is very dependent upon public dollars and those dollars have been reduced a great deal in the last few years and that slows us down.

I have visited several places that are doing research in the biotechnology or biologic approach to pest and disease control. But the problem is there is not that incentive there for industry to make that switch because they cannot make the profit from those approaches that they can from chemical-based pesticides.

So, until we can get more nonindustry research dollars into the agricultural sector, that will be a slow transition. That is one that many entities would probably like to see made faster, but it is not realistic, at this time.

Mr. STENHOLM. Mr. Dooley.

Mr. DOOLEY. Mr. Bell, I farm in California and we have instituted some regulations that require us on the farm to maintain a running inventory that accounts for where the particular pesticide or herbicide was used, so that we can verify just exactly what happened, any material or chemical tool of minor use. Does your State of South Carolina have anything like that?

Mr. BELL. No, sir.

Mr. DOOLEY. How about in Illinois?

Ms. DOYLE. We are just getting into the recordkeeping pace, but not as intensively as California. We don't have the diversity in crops, but we do require individual producer records for application, yes.

Mr. DOOLEY. As we move forward with the FIFRA legislation, touching on the chairman's comment about building the consumer confidence, it really goes a long way, I think. In California we have found that it takes a while to accept its initial implementation. It has given us the opportunity to almost in every instance to be able to refute any unwarranted or unfounded challenge.

I know there is going to be some concerns and some objections from some departments of various States. But when we are looking at how we are going to handle some of the public relations problems that we face, that are oftentimes not based on substance but based on perception, this is one thing that we might have to accept and, hopefully, you can explore that with some of your growers.

Mr. Bell.

Mr. BELL. We as an organization, we generally do support it, sir. In fact, we were accused of using a great deal more chemicals on some of our crops than we actually used, by the assumption that we are using maximum dosage at every available opportunity, and that is not the case.

Mr. DOOLEY. I have no further questions.

Ms. DOYLE. To add to that, one of the recommendations our organization made for enhancing this bill was to increase certification and training in the States for applicators which would, of course, include the recordkeeping.

Mr. STENHOLM. Mr. Canady.

Mr. CANADY. No questions.

Mr. STENHOLM. Mr. Gunderson.

Mr. GUNDERSON. Thank you, Mr. Chairman. I have two questions. They focus on my continued belief that by the time we get done with the next panel we will have so polarized this debate that they will all leave here this afternoon fully committed to doing nothing for the next couple of years.

Question one, can any of you give me ideas, either today or in the future, of what provisions in H.R. 872 you find acceptable? That is probably not a fair question to ask off the cuff, but would you be willing, as organizations, to look at H.R. 872 and find out which provisions you find acceptable?

Mr. BELL. I will respond for the American Farm Bureau Federation. We are on the record as favoring H.R. 1627, however, on any compromises, our staff people will be glad to take a look. But, we much prefer H.R. 1627.

Mr. GUNDERSON. I fully got that message. I am trying to figure out how we get something passed in the Congress. I have been here for 13 years, and this stuff just never goes anywhere. We do this each year and then we don't go any further than the hearings.

Frankly, I am sick of the issue. I would like to try to find a way to get something done.

Don't worry, I am going to ask the next panel the opposite on H.R. 1627, because their testimony tells us everything that is wrong with it. I want to know what parts of that they can live with. If we can take the parts of H.R. 1627 they can live with, and the parts of H.R. 872 you can live with, we may finally have the beginning of a discussion. I don't know, but its worth a try to see what people are willing to give.

The second question is along that same line. What is the biggest need each of you have as an organization regarding the modernization of FIFRA? What is the biggest handicap you face today by continuing the present policy?

Ms. DUGGAN. I will be happy to answer that question. I think there are several things. The largest handicap would be living under the ninth circuit court decision which EPA maintains would require them to start removing wholesale, otherwise, safe chemicals from the marketplace.

We have tremendous concerns of what that would do to the availability, quality, and costs of fresh fruits, vegetables, and grain products. Continuing under current policy, the current court decision and EPA's interpretation of it, would be a very bad public policy outcome for the National Food Processors Association.

We think this is a historic Congress which gives us, for the first time in a long time, a real opportunity to pass a comprehensive pesticide bill.

We would like to take advantage of the goodwill expressed in this hearing, and the interest of the Energy and Commerce Committee, to make sure that we do them in tandem, the Food, Drug, and Cosmetic Act and the FIFRA portions together.

Mr. BELL. Certainly, I would endorse what the lady has said. The Delaney clause, of course, is of great concern to us. The loss of minor-use pesticides and the inability to get replacements because of the costs, those are two areas we feel desperately need attention quickly.

Mr. GUNDERSON. How do you suggest we deal with the cost of minor-use pesticides?

Mr. BELL. I am not sure I can fully respond to that. Some way or another we have to have some way to accept science and not continually go back and add the bureaucratic burden on top of the companies that are producing. Perhaps it might have to be through some sort of supportive assignments.

Mr. GUNDERSON. Mr. Gardner.

Mr. GARDNER. Thank you for asking the question, Mr. Gunderson, because I think the installation of a balanced and workable negligible risk policy is probably the most important thing that needs to be done. I was in the Government 9 years with the Food and Drug Administration before I took my present job.

I testified last week at another hearing on a related subject. One of your colleagues asked me, what is wrong with Delaney, you have lived with it since 1958. I thought of better answers than the one I gave him, which is that we have not lived with it. We have struggled with it. I can tell you at the time I was with the Food and Drug Administration, we worked every day to try to make sense out of that to keep from doing some dumb thing that would totally disrupt the food supply.

I think that the agency and the Food and Drug Administration today have the same problem. By not revising the law to provide a negligible risk policy. We make the agencies, the public, and the Government all look foolish. The public all wonder what is going on here, why can't you do a better job of it? The one act that the Congress could do that would fix this situation is to build into law the kind of negligible risk policy that is in H.R. 1627.

Mr. GUNDERSON. Thank you.

Mr. STENHOLM. Mr. Inslee.

Mr. INSLEE. I just wanted to give you an opportunity to comment. I read in some of the testimony of some of the other panels that follow you, a suggestion that there is an imperfection in this bill that did not allow EPA to consider the multiplier effect of multiple pesticides. I just wondered if you could respond to that.

This may be too technical, but there was some suggestion that somehow this bill would not allow EPA to consider the fact that in fact we ingest multiple pesticides. Does that ring a bell?

Ms. DUGGAN. Thank you for asking that question, Mr. Inslee. H.R. 1627 does not preclude the agency from addressing any toxicological concern. It doesn't compel them specifically to address this issue, but it provides maximum flexibility for the agency to conduct risk assessments according to science.

Probably Mr. Lehman said it better than anyone here, what this bill is about is letting science decide. If there is evidence as to the way in which an assessment should be conducted of chemicals, then this bill would certainly allow EPA to do it that way.

This bill does not prevent or direct them to do it. They have discretion to do what needs to be done according to scientific evidence.

Mr. GARDNER. If I could just ride on that answer, I think that answer is one we support. The fact is that the bill does not prohibit the agency from using whatever good science directs it to use. In fact, risk assessment, as it is applied today by the Environmental

Protection Agency and by the Food and Drug Administration, was an invention of Government.

I will ride on my own record a little bit, risk assessment was introduced while I was serving with the Food and Drug Administration in 1973. As far as I know, it was the first formal approach to using risk assessments for the control of chemical safety in the food supply. If you allow the agencies to do their job with a flexible, scientific policy, they will do it.

Mr. STENHOLM. Ms. Duggan, the recent National Academy of Sciences' report recommends an extra safety factor of up to 10 be included for exposure levels to take children's diets into account. Should this be done, and would H.R. 1627 prevent this from being carried out in a regulatory fashion, if need be?

Ms. DUGGAN. I don't believe that H.R. 1627 would prevent it from being carried out. As I mentioned to Mr. Inslee, the purpose of the national risk standard in H.R. 1627, would be to give EPA maximum flexibility to conduct risk assessments and make regulatory determinations based on science.

One of the hallmarks of the National Academy of Sciences' recommendations is that from everything we can tell, virtually all those recommendations can be carried out administratively and do not require legislation to be accomplished.

Therefore, we are very eager to work with the administration to see which of those can be introduced into risk assessment decision-making sooner rather than later, particularly on the data questions. I think there is a lot of room to discuss and consider what kind of safety factors should be adopted in light of the NAS study and we are willing to do that.

Mr. STENHOLM. Mr. Volkmer.

Mr. VOLKMER. There was one thing said by the gentlemen from Wisconsin about perhaps if we get those who feel one way together with those who feel the other way, maybe we can land in the middle somewhere. Part of the problem I have with the standards that have been in place for a long time, many years, is now there is the question of the Delaney clause trying to get to a place other than where we are right now with the Supreme Court decision.

As I understand the legislation you are addressing today, basically it is a "negligible risk," while, as I understand, the people on the other side would like to have a definitive number. Do you see any problems with a definitive number, whether it is 1 part per million, 1 part per billion, 1 part per 2 billion, as against "negligible risk"?

Mr. BELL. I will respond from our perspective, sir.

Yes, sir, there very definitely is. We are tying in current day science and not allowing for improvements in the future.

Mr. VOLKMER. You say you will take it anywhere the Supreme Court does, but you are willing to say 1 part per million, that doesn't necessarily mean 1 part per million or 1 part per trillion. But you are saying that the negligible risk would be the same as 1 part per million. Do you have a problem with that?

Mr. GARDNER. I would like to try to deal with that question, Mr. Volkmer. It is not so much a number that is important as what goes along with the number. The kinds of assumptions made in determining risks and the kinds of scientific data that are included

in the way those data are weighted or evaluated by the people who are making the assessment, is what is important.

The more specific the provisions of the bill get with respect to how the science should be carried out, the worse that bill is because it prevents the agency, the scientists in the agency, from applying contemporary science as it is understood and has been developed until that point. You need to allow the scientists in the agency the maximum amount of flexibility so they can do what is right. Providing a specific number or other specific provisions as to how the science should be supplied, is not in the best interests of the American people.

Mr. VOLKMER. In other words, what you are saying is that being specific, you say that any additive that would be carcinogenic as to 1 part per million, if it is and, say, it is used on mice or rats, on anything else you can extrapolate, you are saying then that is not good science?

Mr. GARDNER. That is my opinion of it. It is not just my opinion, there are a number of scientists who believe very strongly that is the wrong way to proceed.

Mr. VOLKMER. Thank you, Mr. Chairman.

Mr. STENHOLM. I thank each of you.

We will look forward to working with you in the days ahead.

We will call panel 3.

Ms. Maureen Hinkle, director, agricultural policy, National Audubon Society; Jay Feldman, executive director, National Coalition Against the Misuse of Pesticides; Richard Wiles, director, agricultural pollution prevention project, Environmental Working Group; and Erik D. Olson, senior attorney, Natural Resource Defense Council.

We look forward to hearing each of your testimonies today. Again, each of your entire written testimonies will be made a part of the record. We look forward to hearing your summation.

The first witness will be Ms. Maureen Hinkle, director, agricultural policy, National Audubon Society.

STATEMENT OF MAUREEN KUWANO HINKLE, DIRECTOR, AGRICULTURAL POLICY, NATIONAL AUDUBON SOCIETY

Ms. HINKLE. Thank you, Mr. Chairman and members of the subcommittee.

The National Audubon Society believes that it is in our best interests and all of those who testified today, to try to help you to provide EPA with the authorities necessary to do a good job. Continuing gridlock harms all of us. Congress holds the key to unlocking that gridlock.

The proposal that you have asked us to comment on today is H.R. 1627, the Food Quality Protection Act of 1993, cosponsored by, as you pointed out, a majority of your subcommittee members, 12 of the 22 subcommittee members.

Since introduction of H.R. 1627, the National Academy of Sciences' long-awaited study on Pesticides in the Diets of Infants and Children has been released. We believe that the recommendations made by that scientific body need to be integrated in any legislative change to either FIFRA or the Federal Food, Drug, and Cosmetic Act.

The academy report found that infants and children are different from the rest of the population, both in regard to their vulnerability to toxicants as well as in their patterns of dietary exposure to pesticide residues.

The protection of infants and children is necessary and possible, and their report specified how such protection can be afforded by the three relevant agencies.

We will focus our comments on the recommendations of the academy report and how they have been responded to by H.R. 1627, and some aspects of H.R. 1627, and also the response to the 1987 Delaney paradox report.

Audubon believes that the presence of deliberately added carcinogens in our food and water should be progressively eliminated by the appropriate agencies. The problem has been over the past 20 years how and where to make progress, as more and more carcinogens are detected in our food and water.

The Delaney clause and the Federal agencies directed to implement it, have failed to protect the public from dietary exposure to carcinogens in a dozen ways, which have been used to circumvent the Delaney clause.

Nevertheless, the 1987 report did demonstrate how we could reduce this load in a manageable way. H.R. 1627 responds to the Delaney paradox by giving EPA the discretion to determine what is a negligible risk for all uses of a pesticide. H.R. 872, the Kennedy-Waxman bill, would establish a uniform standard of risk reduction, including other elements of dietary exposure such as drinking water. The National Audubon Society, not surprisingly to you, does support H.R. 872 because, with improvements, it establishes a firm "bright line" based on scientific analysis of the chemicals in question. We believe that allowing EPA discretion to interpret what is negligible invites political pressure on the Administrator. As one observer put it, at decision time, "He or she freezes at the wheel." Unless Congress specifies how to calculate risk, the course of least resistance becomes the norm, and agencies inevitably fail to protect public health adequately unless court action or public outcry ensues.

We believe that a phased risk reduction scheme is necessary in order to ensure that negligible risk does not become acceptable risk, in other words, gradually raising the level of carcinogens that is deemed acceptable. Requiring a 10 to 15 percent per year reduction in carcinogens would result in meaningful reduction.

There are several recommendations of the recent infants and children's study that we think could be employed in the legislation to ensure that infants and children are protected. The report recommended that a 1,000-fold safety factor should be employed to protect infants and children "when data for toxicity testing relative to children are incomplete."

The academy report also recommended that tolerances be based more on health considerations than on agricultural practices.

The agricultural override has become the norm for the U.S. population as a whole which leaves infants and children even less protected. The academy report recommended that "total intake from all foods on which residues may be present should be calculated

when estimating exposure of infants and children." No allowance for treatment of multiple food residues is made in H.R. 1627.

"Because infants and children are subject to nondietary sources of exposure to pesticides, it is important to consider total exposure to pesticides from all sources combined," including drinking water and air.

The academy recommended that estimates of total dietary exposure should be refined to consider intake of multiple pesticides with a common toxic effect. H.R. 1627 provides only for consideration of dietary exposure levels to individual pesticide chemical residues.

We have comments on individual sections of H.R. 1627 to which we have a very strong objection.

In conclusion, we feel that the prohibition on States to take action to protect their own citizenry together with the discretionary interpretation of what is negligible risk is tantamount to deregulation of pesticides and, therefore, we oppose H.R. 1627.

Thank you.

[The prepared statement of Ms. Hinkle appears at the conclusion of the hearing.]

Mr. STENHOLM. The next witness is Mr. Jay Feldman, executive director, National Coalition Against the Misuse of Pesticides.

STATEMENT OF JAY FELDMAN, EXECUTIVE DIRECTOR, NATIONAL COALITION AGAINST THE MISUSE OF PESTICIDES

Mr. FELDMAN. Thank you, Mr. Chairman.

As you know, Mr. Chairman, I am not a member of the cheerleading squad for H.R. 1627 and the negligible risk standards. What I would like to do today is bring a message to the subcommittee with the ground rule that everyone here promises not to shoot the messenger.

The elements that Mr. Lehman addressed, I would like to address as well. He pointed out that there are four elements to the bill: Negligible risk, consideration of benefits and regulatory process, uniformity and speeding up the cancellation process.

I would like to go through those issues as well, starting with negligible risk. It is our belief that we must stop thinking about food safety in the vacuum of residue of rhetoric and the tolerance in the process and start addressing issues of food safety in a holistic manner, by considering the long-term need for chemicals and sound agricultural systems that are not only better for the food consumer, but protective of farmers and farmworkers.

To start, we believe we must set a date by which we will remove from the market cancer-causing pesticides used in food production. Until that date, we should prepare for the transition to alternative methods of pest management that do not rely on pesticides.

This position grows out of our belief that public policy should err on the side of public health and safety, not rhetoric based on uncertainty of safety thresholds or poor pesticide exposure assumptions.

In our testimony, we cite the background for the poor pesticide exposure assumptions. Basic to this position is the fact that delaying the Delaney clause of the Federal Food, Drug, and Cosmetic Act is contrary to what you have heard today based on sound science, with human experience confirming laboratory animal studies on cancer effects.

Mr. Chairman, members of the subcommittee, in the years since the ninth circuit court decision upholding the Delaney clause, the provision has been called outdated and anachronistic by politicians and industry interests.

However, our testimony tries to lay out for you, and we believe this deserves careful consideration, the fact that the law, the Delaney clause, is based on a scientific understanding that we cannot prove the level at which a cancer-causing substance initiates a cancer effect, whether it be a promoter or an initiator, although we can determine that a chemical is a carcinogen.

Those arguing the Delaney clause demise, that you heard today, would replace it with a negligible risk standard as proposed in H.R. 1627. The negligible risk standard is steeped in the risk assessment method and herein lies the problem. These methods are filled with uncertainties, miscalculations as to sensitive population groups such as children and elderly, average body weight, consumption patterns, and other exposures affecting the total toxic load that any one individual already carries.

On to benefits: Inherent in H.R. 1627 is the standard inherent in FIFRA, which is the unreasonable adverse effects standard. In light of the NAS report, we believe the standard is outdated in not recognizing the need for protecting sensitive population groups and reducing pesticide groups in our society.

In fact, if you look at FIFRA, which is incorporated in H.R. 1627, there is an efficacy waiver on pesticides. All efficacy data on pesticides is now waived by EPA except for disinfectants. Similarly, the law does not require performance data unless problems with the pesticide, such as Benlate in Florida, which farmers there have tied to billions of dollars in devastating crop damage, would not show up in the EPA's review.

Neither would information about pest resistance, now widespread in insects, weeds, and rodents, or secondary pest infestations. All these factors affect the ability of the pesticide to perform as intended and thus deliver a benefit.

Let's move now to streamlining. We agree with the intent of the bill to streamline the cancellation processes. However, H.R. 1627 falls short of requirements needed to move the process along expeditiously, to do so in a manner that ensures full, open public participation with health and environmental standards that are protective of the public health and environment.

We cite for you Mr. Rose's bill of last session, H.R. 3742, in which he lays out a very specific timeframe, I believe it is 18 months, for a conclusion, which this bill does not do.

Now, Mr. Lehman also addressed the issue of uniformity or preemption. There, too, we would make the statement which you have made previously in this subcommittee, that preemption is undemocratic. It is inappropriate to leave States out of the process, to play a meaningful role in that process. Historically, States have played a very valiant role in the process of setting standards.

In conclusion, we have an opportunity here, Mr. Chairman, to change the way we regulate pesticides and meet food production and nutritional needs of the public, while meeting the productivity and profitability needs of those who grow food.

We have joined with many other environmental groups in adopting the pesticide reform agenda, which we would like to enter into the record today.

We have also previously presented to the subcommittee our outline for a Federal Pest Management Act which takes a holistic look at pest management and the social and health costs associated with pesticide dependency.

In conclusion, I would like to say the question really before us is whether we as a nation can afford to maintain a course of dependency on highly toxic pesticides with policies that tinker with a flawed risk assessment approach. We do not think so. We may feel good about what we have accomplished in the short run, but we have failed our children, future generations, and the sustainability of the planet if we proceed down the course proposed in H.R. 1627.

Thank you.

[The prepared statement of Mr. Feldman appears at the conclusion of the hearing.]

Mr. STENHOLM. Mr. Richard Wiles, director, agricultural pollution prevention project.

STATEMENT OF RICHARD WILES, DIRECTOR, AGRICULTURAL POLLUTION PREVENTION PROJECT, ENVIRONMENTAL WORKING GROUP

Mr. WILES. Thank you, Mr. Chairman.

Thank you for the opportunity to testify today on H.R. 1627. I am Richard Wiles, director of the agricultural pollution prevention project at the Environmental Working Group, a nonprofit environmental research organization here in Washington, DC.

We oppose H.R. 1627 for reasons I will detail below.

Instead, we support H.R. 872, the Pesticide Food Safety Act of 1993, H.R. 872, the Pesticide Food Safety Act of 1993, introduced by Mr. Waxman, with strengthening amendments. H.R. 872, and its companion bill, S. 331, introduced by Mr. Kennedy in the Senate, provides special protection for children, establishes a strict health based standard for pesticide residues in food, and implements many of the key recommendations of the National Academy of Sciences' committee.

The pesticide regulatory system is built on the notion of maximum acceptable risk. The goal is not to produce abundant and affordable food using the least amount of pesticides possible; rather it is to set and allow maximum acceptable levels of human and environmental exposure to hundreds of pesticides in thousands of formulated pesticide products applied to hundreds of food and feed crops. The foundation of this paradigm is the untenable notion that scientists and regulators can accurately assess the risks from residues of 20,000 different formulated pesticide products all interacting in the environment and the human body.

Not only is the basis of this process highly implausible, it is extremely expensive. It provides no incentives for agricultural production innovation, and allows maximum opportunities for delay; it is extremely bureaucratic, unpredictable, founded on misplaced burdens of proof, and divorced from market forces. It captures all

of the bad elements of failed regulatory policies in other areas; it can be rightly characterized as "end-of-the-pipe" regulation for food.

H.R. 1627 enshrines into law, all of the bad features of current policies. Beyond these general flaws, we oppose H.R. 1627, the Lehman, Bliley, Rowland bill, for many specific reasons.

Some of the most important are as follows: H.R. 1627 is bad for children. It does not require specific protection for children; it does not ensure that exposure to pesticides at legal limits is safe for children. In fact, H.R. 1627 does not implement a single finding of the NAS committee report; it does not require an assessment of exposure from all sources, as recommended by the academy panel, nor does it include any special methodologies or safety factors to protect children, as recommended by the NAS panel.

H.R. 1627 is bad for the public health. H.R. 1627 repeals the Delaney clause of the Federal Food, Drug, and Cosmetic Act, the most protective, albeit imperfect, preventative public health standard in Federal law. It is replaced with the weak, ineffective, and entirely subjective risk benefit standard currently contained in the Federal Insecticide, Fungicide, and Rodenticide Act.

H.R. 1627 codifies in law the current regulatory bias toward agricultural benefits, and fails to acknowledge the need for greater protection of the public health, as recommended by the NAS committee report. H.R. 1627 specifically allows economic benefits to farmers to justify public health risks in excess of the level determined as negligible by the EPA. H.R. 1627 does nothing to reduce the use of pesticides. On June 25, 1993, the Clinton administration announced a historic shift in pesticide policy, declaring a commitment to pesticide use reduction and the promotion of sustainable agriculture. H.R. 1627 does nothing to advance this goal.

The EPA currently establishes food tolerances by adding up the risks presented by all food uses of a pesticide. H.R. 1627 appears to weaken this standard by requiring that exposure calculations are reduced to a single pesticide on a single food. H.R. 1627 further does not respond to the recommendations of the NAS committee to include all routes of exposure—food, water, garden, and home applications—in the establishment of food tolerances.

All food production and pesticide regulatory policies should work coherently toward the same goal; producing food with the least amount of pesticides possible, and where appropriate and reasonable, no pesticides at all. This goal should be accomplished at the least cost to taxpayers, consumers, and farmers.

Within this framework, certain specific policy changes must be made: Pesticides that pose unacceptable risks to children and other high-risk populations must be phased out; pesticides that remain on the market must meet strict health-based criteria designed specifically to protect children and other sensitive or highly exposed groups; USDA must embark on an initiative to provide pest control alternatives to growers of crops most dependent on pesticides that present the greatest risks to human health and the environment; and consistent and enforceable market incentives that reward growers for reduced and low pesticide use must be established.

H.R. 1627 accomplishes none of these goals, and erects significant obstacles to their achievement. We therefore, strongly oppose its enactment.

[The prepared statement of Mr. Wiles appears at the conclusion of the hearing.]

Mr. STENHOLM. Mr. Erik D. Olson, senior attorney, Natural Resources Defense Council.

STATEMENT OF ERIK D. OLSON, SENIOR ATTORNEY, NATURAL RESOURCES DEFENSE COUNCIL

Mr. OLSON. Thank you.

I wanted to start by expressing our appreciation for your support and also to say that I think there are some concepts in H.R. 1627 that deserve further enrichment, thought, and development that in the spirit of Mr. Gunderson and other member's questions that I think we ought to talk about.

One is the provision on integrated pest management, which does need beefing up. As has been mentioned, the Clinton administration has proposed that we start shifting to alternatives and reducing pesticide usage. We believe we need to build on the Clinton administration proposals and develop a full-scale program for shifting to less risky methods.

In addition, the provision on data collection needs to be built upon, but the concept of requiring recordkeeping is a good one, and as was suggested earlier, we believe there is a need for a strong reporting program nationally.

Reform of certain aspects of the FIFRA provisions for cancellation and suspension of dangerous pesticides is badly needed. Although we believe the provisions in the Rose bill introduced last year are preferable to H.R. 1627, we appreciate the spirit in which the proposal has been made to streamline cancellation and suspension.

There are, however, of course, many things that have been mentioned that we are concerned about in H.R. 1627. I will not go into incredible detail on them, but I will simply list the eight major areas of concern for us.

First and most fundamental is the override of health considerations by agricultural benefits. We are concerned as we lay out our health costs that this would allow arguments that virtually any pesticide residue should be allowed simply because the pesticide's removal from the market might have an impact on some uses of pesticides under certain circumstances.

We are concerned that the term "negligible risk" is not defined. As has been mentioned, the question of whether to accept a 1 in 1-million risk of getting cancer is a policy question.

Should we or should we not allow a certain number of cancers? That is a policy question, a question that Congress is well-equipped to deal with. It is our view that the policy questions should not be kicked into the Departments but should be dealt with by Congress.

The Lehman-Bliley bill enshrines the negligible risk concept. We are very concerned about this factor with pesticides because of uncertainties in how risk assessments are done.

Certainly, we are concerned about the failure of the legislation before the subcommittee to specifically require that children be protected.

The bill allows consideration of reasonable assumptions and data on identifiable subgroups of the population. Our concern is that it does not require that children be protected.

EPA will tell us and has said on many occasions that it does consider children. However, the National Academy of Sciences said while EPA may consider children in some circumstances, their policies do not protect children in some circumstances.

The Lehman-Bliley bill apparently requires the establishment of tolerances based exclusively on dietary exposure to the pesticide from the single food at issue. The single food issue is a significant one.

In H.R. 1627, it repeatedly refers to the pesticide chemical residue as the tolerance which shall be deemed to be adequate if that particular residue is found to fit the standards. That is where our concern comes from. It would only authorize evaluation of a single pesticide on a single food.

If you read the language carefully, that is quite likely how the court would interpret it. We are concerned about the failure to consider multiple pesticides that have the same toxic effects, which is recommended by the National Academy of Sciences to be reviewed and looked at. The National Academy of Sciences said it should not be ignored just because the data are inadequate.

Finally, the provision that preempts the State's ability to move forward to protect their citizens from dangerous pesticide residues through more stringent tolerances if the States find it is necessary we find unjustified and unnecessary.

Thank you very much for this opportunity, Mr. Chairman.

[The prepared statement of Mr. Olson appears at the conclusion of the hearing.]

Mr. STENHOLM. I thank each of you for your testimony.

Mr. Smith.

Mr. SMITH of Oregon. Thank you, Mr. Chairman.

Mr. Wiles, should we stop eating any kind of foods that have been treated with pesticides that are carcinogenic?

Mr. WILES. No. The issue is one of making it safer. I think we all agree on that. That has created some cooperation.

Mr. SMITH of Oregon. So we are assuming some risk of cancer?

Mr. WILES. In doing what?

Mr. SMITH of Oregon. In your statement, you are assuming some risk of cancer by allowing people to eat certain foods?

Mr. WILES. Yes.

Mr. SMITH of Oregon. So the question is not is there a risk of cancer; it is how much risk?

Mr. WILES. That is correct.

Mr. SMITH of Oregon. The Delaney clause says zero risk. We are assuming Delaney is outmoded. Most people believe it is.

Would you accept the fact that Delaney has zero risk and, therefore, it is not applicable to today's standards?

Mr. WILES. We don't think the Delaney clause per se is the appropriate standard, but largely because of the inequitable treatment of different foods. We support a gradual but complete movement away from adding carcinogenic pesticides to the food supply.

We think it is important to provide farmers with alternatives. We would be glad to work with you in developing these alternatives.

Mr. SMITH of Oregon. I understand your point. We are all not exactly pure here, that is my point. There is a risk in this, even safe foods.

The question is what is the risk? Delaney is a zero tolerance. We have already admitted that we have accepted a tolerance to do that.

Mr. Feldman, on page 7 of your testimony, I think you indicated that negligible risk is not found in good science. I am interested in that statement, because the National Academy of Sciences, which we all quote, and you all quote, depending on which point we want to make, advocates negligible risk. Do you support the National Academy of Sciences?

Mr. FELDMAN. As you say, there are different panels that make up different committees of the NAS. We cite positions we tend to agree with and other groups cite positions they agree with.

The panel which was reporting to the NAS committee did recommend a negligible risk standard. We don't feel it is an appropriate standard because it is a crude measure.

Our conclusion is that we should not lull ourselves into a sense of complacency and that we have established a bright line in which we could leave this hearing room today and assure the American public that we have established a cap on the cancer rate. Negligible risk in H.R. 872, does not enable us to do that. This is a very crude measure.

Our testimony makes certain assumptions of average body weight, vulnerability, consumption patterns, et cetera, that are not calculated.

In the end, we are left with a standard that is not generating a political decision and supporting the political decision I am sure we all would like to make.

Mr. SMITH of Oregon. Is Delaney a crude method?

Mr. FELDMAN. Delaney is scientific in that it has threshold effects of cancer-causing pesticides. We cannot determine the threshold at which a cancer-causing effect is initiated and promoted. Delaney makes the statement that we should not introduce that substance into the food supply and try not to add the additional unknown risk of that material.

Mr. SMITH of Oregon. It seems to me that on the one hand, you are arguing for flexibility, which, as I understand the National Academy of Sciences, at least in their testimony here, advocated some flexibility in determining negligible. But on the other hand, I have you trashing the idea of negligible risk. Which side are you on?

Mr. FELDMAN. We work with farmers and consumers. The goal is to get to a standard, institutionalize the unnecessary use of poisonous materials.

Mr. SMITH of Oregon. I understand. I am trying to get at your field.

Mr. FELDMAN. We cannot assume that given the known deficiencies—

Mr. SMITH of Oregon. The scientists testified in favor of it.

Mr. FELDMAN. There are people who believe we can bring down the risk of eating food by adopting a negligible risk standard.

Mr. SMITH of Oregon. My problem is who do you believe?

Mr. FELDMAN. They are saying we can bring down the risk.

Mr. SMITH of Oregon. I cannot figure out who to support, you or the National Academy of Sciences.

Mr. FELDMAN. The easy thing to do is to identify how we can get to the national goal of eliminating unnecessary use and this bill does not do that, unfortunately.

Mr. STENHOLM. Mr. Dooley.

Mr. DOOLEY. Mr. Wiles, you commented that Delaney was imperfect. In what ways do you mean?

Mr. WILES. The central imperfection that I cited was that it has a bias against processed foods. It is not consistently applied to all foods.

Mr. DOOLEY. So if it applied to all foods, you would say Delaney would be perfect?

Mr. WILES. I don't know if I would say it would be perfect. We support the goal of phasing out carcinogenic pesticides that are added to the food supply, so I suppose I would. I would not say this is something that we should try to do next Tuesday or immediately. What we are saying is it is something we should be working toward.

Mr. DOOLEY. So what you are saying, then, you do not accept in any way the concept that there is a negligible risk that could be tolerated as public policy?

Mr. WILES. I don't think that is what the policy should be. If you want to have a discussion about the science, I think that it is perhaps—

Mr. DOOLEY. No, I am saying, as a public policy, what you are saying is that the appropriate public policy would have zero risk.

Mr. WILES. Not zero risk.

Mr. DOOLEY. Then a negligible risk.

Mr. WILES. The appropriate policy is to drive toward the phase-out of substances that we know cause cancer. That is the appropriate policy. We may never get there, but the goal should be to eliminate the addition of carcinogenic pesticides from food.

Mr. DOOLEY. Ms. Hinkle, does your organization support some form of negligible risk.

Ms. HINKLE. We believe that as the National Academy of Sciences recommended, negligible risk offers a manageable way of reducing the load of carcinogens. That is its major contribution. It is to break the logjam. It is to start the process. We have to start from where we are. We do not want to create economic dislocation or massive chaos. So in order to reduce carcinogens in an orderly way, negligible risk is a way to reduce the load.

Mr. DOOLEY. So you would, then, advocate moving from a Delaney zero risk to a negligible risk standard?

Ms. HINKLE. As long as it is phased out so that you don't start accepting what is there.

Mr. DOOLEY. Mr. Feldman, you obviously don't accept there should be any risk.

I have also introduced a bill dealing with public health materials. Where we get into, I think, a classic example of where there is ob-

viously tremendous benefits in ensuring a healthier society, healthier environment by eliminating some pests, some diseases that are carried by some pests which can be eliminated or controlled by the use of some poisons, pesticides, that might have, at some level, a negligible risk.

Does this not, even in an instance such as this, there should not ever be any consideration of the benefits of a material?

Mr. FELDMAN. We agree with you that there should be consideration in weighing in certain circumstances. The problem with this legislation is that there is no mandated requirement that there be an assessment as to the range of less toxic alternatives that might achieve either a public health goal for a food production goal to establish what we consider a faulty line, a negligible, and then call that a so what level and allow the use of chemicals that have, in some cases, exceedingly high risks up to that so what level ignores the fact that there may be, and often in our experience there is, and are in multiple cases alternatives to that cancer causing pesticide.

Mr. DOOLEY. I understand you correctly, though, that you would state if the only way to control this pest that might be a public health nuisance, if the best alternative at that point did have some level of risk of being a carcinogen that if we considered all the alternatives and it was the best alternative, you would then say it is appropriate to consider the benefits.

Mr. FELDMAN. I would say that if there are situations in which the adverse impact of the public health situation that we face is worse than the exposure to a chemical of the nature you are describing, then, yes, we would have to make that public health decision.

Mr. DOOLEY. I guess this gets at, and Mr. Wiles, I would have to take exception with your comment that we basically have a policy now which I think you used the maximum acceptable dose. And I guess my disagreement with that, or concern with that, is that we utilize this maximum tolerated dose mechanism in order to try to determine whether or not a product is a carcinogen. And it is a policy which is put in place almost by default because even the National Academy of Sciences agrees it is not the best policy out there and we should be able to develop something better than that.

But then, even though once we go down that path and we go through the testing, where there might not be any incidences of any carcinogenic impact until you get at the very highest levels, that is extrapolated going back to where you take into consideration that every product, every farmer that used it on every commodity used it at the maximum dose as often as the label would require. And then they back up and say every consumer out there consumes the maximum amount of that product at the maximum number of days and maximum number of incidences, which, in itself, I mean, ensures that there is a tremendous amount of safety factor involved in it.

I just question how you can, in good conscience, make a statement like that when we have more than a hundredfold safety factors on any product that is put out there, and, in most instances, the carcinogenic impact doesn't even show up at normally applied doses.

Mr. WILES. The testimony, perhaps, was misleading. I believe it says maximum acceptable levels of risk. What I am referring to is not maximum tolerated dose testing regimes, but rather the fact that the entire pesticide regulatory system is built on the notion of maximum acceptable risk.

In setting the tolerances for pesticides, the EPA looks at each different pesticide one at a time, one food at a time, and adds up the risks of all those foods to arrive at the maximum acceptable risk level from that pesticide. This is done across the board for each pesticide allowed on food.

My comment is merely to point out that there is nothing in the current Federal pesticide regulatory system that is driving us toward the least pesticides that are required to do the job. Instead, we set these maximum acceptable health limits based on safety factors that some people think are conservative enough and other people do not. I was not criticizing the maximum tolerable dose testing regime, but rather the current tolerance setting system which is based on the notion of maximum acceptable exposure.

I will say, though, that perhaps the most basic conclusion of the National Academy of Sciences committee was that exposure at the tolerance levels should be safe for children, period, and that anyone should be able to consume food with residues at the maximum legal limit, every day, without encroaching on safety margins.

So I am sorry for the confusion there. I agree with you. Maximum tolerated dose testing regimes can be problematic and they can sidetrack the agency into regulatory analyses of chemicals that may not be ones that we should be spending a lot of time on.

Mr. DOOLEY. My time is up, Mr. Chairman.

Mr. STENHOLM. Follow up on that, Mr. Wiles. You stated a moment ago, and I want to see if there is concurrence of each of the four of you, and to follow up on that previous statement, the National Academy of Sciences testified before this subcommittee, and I believe they said publicly, and I believe you indicated your agreement, that you would not recommend the removal of any of our current food supply from children as a result of any of the scientific evidence that was placed before us either through the National Academy of Sciences or any other information that we have available to us today.

Mr. WILES. Right. We believe the health risks of not eating fruits and vegetables are greater than the pesticide risk.

Mr. STENHOLM. For children today.

Mr. WILES. Based on what we know, right.

Mr. STENHOLM. Mr. Olson, do you concur with that?

Mr. OLSON. I guess our basic problem is for a lot of these chemicals we have not gone through the risk assessment. The risk assessment has not been made public—

Mr. STENHOLM. Simply answer my question as to the statement of Mr. Wiles.

Mr. OLSON. My answer is that we don't know for a lot of foods, because we have not seen the risk assessments. We have not seen what the levels of risk are.

Mr. STENHOLM. So, then, you recommend that children not eat certain—

Mr. OLSON. No.

Mr. STENHOLM. You recommend that it is OK to eat them? You do not know?

Mr. OLSON. Our statement has repeatedly been that children should eat fruits and vegetables, however, I cannot say with any conclusive evidence whether there are any fruits or vegetables that may encroach on safety margins because assessments have not been made available.

Mr. STENHOLM. That is a fair statement. Mr. Feldman.

Mr. FELDMAN. We urge people to find the nonchemical path where possible. So we urge people to find organic food, if they can. And where they cannot, they must continue to eat for sustenance.

The point of the report and the point of your question, I think, is that we should try to bring down the levels of risk and we should remove unnecessary pesticides as a matter of policy. But as a matter of survival in the short term, people have to eat. They should seek out organic food where possible.

Mr. STENHOLM. Ms. Hinkle.

Ms. HINKLE. I also believe that people should not stop eating fruits and vegetables.

Mr. STENHOLM. Even children now, is what I am saying.

Ms. HINKLE. Even children.

Mr. STENHOLM. Based on what we know. There are a lot of things we don't know and this subcommittee certainly agrees we need to pursue the answers to those things we do not know.

Ms. HINKLE. As the academy pointed out, children eat more fruits and vegetables than the average 19-year-old male and they need that kind of diet. What we urge is that the potent carcinogens be phased out as rapidly as possible so that we can reduce the potential problems that infants and children face.

Mr. STENHOLM. Mr. Gunderson.

Mr. GUNDERSON. Thank you, Mr. Chairman.

I understand three of the four of you indicated there were some things in H.R. 1627 that were good and that you would all be willing to submit some recommendations to this subcommittee on what parts of H.R. 1627 you would find acceptable; is that correct?

Ms. HINKLE. Trying to be positive.

Mr. STENHOLM. With certain improvements, is what I understand.

Mr. GUNDERSON. I realize it is a leading question.

Mr. SMITH of Oregon. They like the title.

Mr. GUNDERSON. They like the title? OK.

Ms. HINKLE. We like the intent of certain provisions.

Mr. GUNDERSON. All right. I don't think I will be in Congress long enough to see this resolved, but maybe, just maybe.

What do you define as "negligible risk?" Can you give me a parts per million, trillion? How would you define "negligible risk?"

Mr. FELDMAN. I will try. Negligible is a standard by which we determine acceptable level, acceptable rate of cancer. Our definition of what exposure results in, an acceptable rate of cancer.

So, obviously, implied in that is we have to come up with some exposure formula that enables us to reach our acceptable rate of cancer. One in 1 million, one excess cancer per million population exposed or one excess per 100,000 exposed. Whatever. Pick your number.

Mr. DOOLEY. Just to interrupt here for a second, and thank you for yielding, Steve, but that was the point I was getting at earlier, is that it is not as simple as a policy of what is the acceptable level of cancer, incidents of cancer, because that is what I was driving at on these public health views, and you agreed once we considered all the alternatives, and if the benefits of utilizing this material outweighed some of the risk of this cancer, incidents of cancer, then it gets a lot more complicated than just having a simple number out there, as you just implied.

Mr. FELDMAN. Right. I will think what you described to me was an exception, an exception to the rule. We are talking here about agricultural production, generalized food production. We can talk along the way, we can talk about exceptions, public health exceptions, exceptions in emergencies, et cetera. But here we are talking about a generalized policy for food production and the resulting residues on those food commodities. And I think the issue we are facing in the general context system, what are we going to accept as a rate of cancer and then how are we going to determine what exposure results in that rate of cancer.

Mr. GUNDERSON. Let me go on to a different subject. Mr. Wiles, this study that you did, like any study on this issue is going to be controversial. You know that. You have your detractors and your supporters. Did you have any scientific peer review that you can share with this subcommittee? It is no secret some people suggest there is not, and I am trying to be a friend here in that regard.

Mr. WILES. This was not a scientific report in the sense of an academic peer reviewed article. This report is a policy report and it utilized some EPA standard risk assessment methods.

But just as none of the reports produced in this town from the Brookings Institution to the Cato Institute to the Environmental Working Group are peer reviewed in the sense of an academic peer review, blind peer review, refereed by editors of scientific journals, this report was not peer reviewed either in that technical sense. It was reviewed by some of the most eminent scientists in risk assessment and toxicology, but it was not peer reviewed in a technical sense.

Mr. GUNDERSON. One of the things that jumped out to me in looking at the back of your testimony today, because I think what all of us try to do is bring this discussion down as much as possible to basic English, is the debate between H.R. 872 and H.R. 1627. I was struck by your statement that H.R. 1627 allows ag benefits to override the protection of public health in certain situations. Can you give me any language in H.R. 1627 that verifies or substantiates that kind of an allegation?

Mr. WILES. Well, I think it is on pages 36 and 37, section (2)(F) and, (i), (ii) and (iii), if you want to go through that.

Mr. GUNDERSON. I have it in front of me, and if the chairman will indulge me 1 more minute. The first subparagraph says that the, "use of the pesticide that produces the residue protects humans or the environment from adverse effects on public health or welfare." The next one is, "use of the pesticide avoids risk to workers, the public or the environment." The third one, "the unavailability of the pesticide would limit the availability to consumers of an adequate, wholesome, and economical food supply."

And then the concluding paragraph says, "In making the determination under this subparagraph, the Administrator shall not consider the effects on any pesticide registrant, manufacturer, or marketer of a pesticide."

Now, I mean where in there do we say agricultural interests take precedent over public health?

Mr. WILES. I think that agricultural benefits are allowed by omission rather than specifically stated in here.

For example, lines 10 through 13 on page 37, in making the determination under this subparagraph, the Administrator shall not consider the economic effects on any pesticide registrant, manufacturer, or marketer of the pesticide, does not include farmers. At the same time, it does not specifically say the bill is not crass enough to say economic benefits to farmers should specifically override the public health.

Perhaps Erik could take a shot at it.

Mr. OLSON. I will refer you to pages 6 through 8 of our testimony. We describe some of the problems we see with the benefits test. The one that I think is worth looking at is on page 37, lines 3 through 9, in which the bill says that the unavailability of the pesticide would limit the availability to consumers of an adequate, wholesome, and economical food supply, taking into account regional and domestic effects, and such adverse effects are likely to outweigh the risks posed by the pesticide residue.

Our concern is that the language is extremely broad. The example we give in our testimony is that if the removal of that residue arguably would prohibit the use of the pesticide in a certain area in a certain State, the registrant and the grower would argue that it might have some price effect, would argue that it might impose some kind of a regional effect on prices, and, therefore, that it should be allowed to remain on the market.

The concern is that not only by the language of the bill itself, but also past history under FIFRA, suggests that this kind of provision freezes EPA's ability to take action and also gives rise to significant litigation. Our concern is that this essentially could sort of be a pesticide lawyer's full employment act to interpret exactly what this is and could tie up EPA in court for 5 or 10 years before a determination is made as to what that means.

Mr. GUNDERSON. Would you share with us what you believe would be clarifying language?

Mr. OLSON. I don't know what this is supposed to mean if it does not mean what we are interpreting it to mean. If the intent here is to say that if the removal of the pesticides' tolerance for a particular food would result in some kind of economic impact, that is where we think that this would allow the economic impact to override—

Mr. GUNDERSON. Well, let us go back to the beginning. I started this question based on the allegation this allows agricultural benefits to override public health. Mr. Wiles referred to you to look at this particular section and you picked out two provisions, the economics of the food supply and the regional disparities.

My question is if you think economics and regional differences give agriculture too much of a leeway; would you share with this

subcommittee some language that you believe puts that into a more balanced perspective?

Mr. OLSON. I will tell you what our proposal is on this very issue, is that we move toward a phaseout. We would consider these kinds of issues as we move toward a phaseout, but ultimately, the pesticides would be pulled off of the market. They would all have to ultimately meet a health-based standard, and what we have proposed is at most a 7-year shift into alternatives to the pesticide that is imposing the cancer risk. That is the approach that we have urged.

We think that there should be an interim health-based standard, but ultimately that these kinds of considerations would only be taken into account in determining whether there is an alternative or not right now as we move toward the ultimate phase out.

Mr. GUNDERSON. I am out of time, so thanks. Thank you, Mr. Chairman.

Mr. STENHOLM. Mr. Inslee.

Mr. INSLEE. Thank you, Mr. Chairman.

First, I have enjoyed your comments, but I really want to know if your organizations truly mean what you just said, and I want to ask you that specifically. I mean, if we knew today that 8 years from now, despite the most rigorous IPM research and the most rigorous research to find a less toxic substance that you would have no apple crop without the use of a particular pesticide, do you truly, truly urge the public policy of this country to say that we have zero pesticide usage, even though it would mean we would lose the entire crop 8 years from now?

Mr. WILES. I don't think any of us are saying that. We don't want to cause the elimination of any crop 8 years from now. We would all agree, I think, that if famine or pestilence or plague were the alternative, we would take the pesticide.

We are trying to force agricultural innovation toward safer pesticide control practices through Federal law, which we think is a legitimate goal.

Mr. INSLEE. I believe you do approve the 1 in 1 million chance or possibility that is in H.R. 872. Why do you accept any possibility from a known carcinogen?

Mr. OLSON. Our position, which is laid out in this document which we provided to the subcommittee, and it is the position of everyone from the AFL-CIO to the Physicians for Social Responsibility and many environmental groups, is that that standard ought to be a standard that is imposed over the short term and that we should ultimately be moving toward alternatives to the pesticides that cause cancer, for several reasons:

One is the concern that the National Academy of Sciences pointed out of cumulative risk. You have multiple carcinogens. There are multiple endpoints or multiple pesticides that could have the same toxic effect. There are also farmworker risks from the cancer causing pesticides, groundwater and drinking water problems. And unless you have some kind of endpoint, it is our belief that you will not see a major shift in resources to look for alternatives, unless there is some endpoint or drop-dead date that assures that the shift will occur over the long term.

Mr. INSLEE. I guess what I am getting at, I would assume the reason you accept the 1 in 1 million possibility is you do perceive some benefit to some of these chemicals; am I right, at least from the short term?

Mr. OLSON. Clearly, some pesticides have some benefits. I don't think anybody is questioning that. The question is what kind of national policy should we have over than long term, and our long-term view is that we should be moving toward not having an intentional addition of cancer causing pesticides to food supply.

Mr. INSLEE. If you do accept the proposition that we do accept some level of risk because there are some benefits of different chemicals, why do you suggest that we have one level of risk for all pesticides regardless of their benefit? In other words, you accept 1 in 1 million for pesticides that may have no social benefit; you might be able to resolve through an IPM program tomorrow, and yet you set the same level for something that may be entirely beneficial and there is no known or even over the horizon some substitute.

Why is that good public policy? Why not have a risk benefit analysis for each depending on the various benefit for their individual characteristics?

Mr. WILES. In the real world, if we set a public health standard all pesticides would meet, regardless of what it is, 1 in 1 million, 1 in 10 million, zero risk, farmers will then go and determine the economic usefulness of a pesticide.

What we are saying is, where public health standards are required, that they should be set and should be the driving mechanism. Farmers will then determine the economic value of that pesticide within that public health regime.

Mr. FELDMAN. Can I say there is a model for it. This is not the first time this issue came up. Under the Clean Air Act, as you are probably aware, requirement that methyl bromide and other ozone depleters be phased out in the year 2000. That is our model.

We are saying there are some chemicals that are exceedingly dangerous and we, as a society, should not tolerate them. We should put energy and resources into finding alternatives over a reasonable period of time to enable the agricultural community to adjust to forestall economic dislocation and to assist consumers in meeting safety goals.

So this concept is in law under the Clean Air Act and it is one we urge you to take a look at. It identifies a hazard level as unacceptable and puts resources toward finding alternatives.

Ms. HINKLE. Could I just comment, very briefly? We know that 60 percent of herbicides are carcinogenic, 90 percent of fungicides are carcinogenic, 30 percent of insecticides are carcinogenic. We should address ourselves to that heavy load of carcinogens in the food supply. At the same time, we should be putting more funds into public research, and I agree with both Mr. Bell of the Farm Bureau and Ms. Doyle of the NFPA and NASDA, who both urged more dollars in public research. Until we do that, we will not have alternatives for much of this big load of carcinogenic chemicals.

Mr. INSLEE. Thank you.

Mr. STENHOLM. Mr. Feldman, on page 5 of your statement you state, basic to this position is the fact that the Delaney clause of FFDCa is based on sound science.

Now, we have not had very many witnesses, in fact, I believe you are the only one, but I would say there may be a few others that have contended that. Most of the witnesses from the scientific community have testified that the Delaney clause is not based on sound science.

What is the basis for your conclusion that it is?

Mr. FELDMAN. Well, we cite the scientific literature, a number of studies that have gone from looking at the epidemiology of human adverse health effects, cancer, comparing it to laboratory animal studies, cancer testing, showing the efficacy of that approach. But I think the basis of that statement stems from the fact that we cannot determine the threshold effect for exposure to carcinogens.

As with an acute effect like a rash or a headache or something, you can identify the point at which you induce that adverse effect. We cannot do that with the carcinogens for a number of reasons which I would be happy to get into which is contained in the testimony. But if you accept that premise, that scientifically we cannot determine the point at which a cancer effect is seen in test animals or in the human population, then science tells us that we don't know. We simply don't know.

Politicians took that uncertainty and took that lack of knowledge and interpreted a scientific fact that we don't know the point at which a chemical induces cancer and decided when adopting the Delaney clause to err on the side of public health protection. If science cannot tell us when this material induces a cancer effect, then we, the Congress, believe we should not be allowing its introduction into the food supply.

So the fact is, we cannot determine the threshold effect for exposure to carcinogens. It is a scientific fact. I don't think anyone in this room or the scientific community would dispute that. The question, then, is what is the correct political course? And we believe Delaney was the correct political course in evaluating that scientific fact.

Mr. STENHOLM. Ms. Hinkle, you had an addendum to your statement that you say was put in in response to Mr. Gunderson's question in a previous hearing and you list various cancer causing agents in this study, some of which—my chemistry has escaped me—but some of which I do remember a little about. Arsenic, for example. Chromium, cadmium.

Now, I believe that it is correct to say that our bodies contain a certain number of molecules of these chemical compounds normally. Was that not your understanding?

Ms. HINKLE. Not the synthetic—

Mr. STENHOLM. Well, is it your belief that science can determine the difference between synthetic carcinogens and natural carcinogens in the body?

Ms. HINKLE. Yes. We do have many, as the chemical companies say, we are chemical beings and we do have in our bodies organic chemicals. We have zinc in our bodies, but these are naturally occurring compounds in the human body.

Mr. STENHOLM. Arsenic is not.

Ms. HINKLE. Arsenic is not vinyl chloride or bischloromethyl ether or soots and tars, creosote, polychlorinated biphenyls.

Mr. STENHOLM. It is my understanding my body has approximately 100,000 molecules of arsenic per cell as a normal occurrence. That they are in my body regardless of whether I have eaten a food that has had these compounds artificially put upon them or whether it just happens.

That is my knowledge of it, and you are shaking your head affirmatively, Mr. Wiles, that there are certain chemicals that occur naturally in our body.

Mr. WILES. I think that is true, sure. Trace elements and things like that, right.

Mr. STENHOLM. And many of these elements are also carcinogens. Most of them are used, in fact, in the pesticides, herbicides that we, in fact, use. Or at least some of them. Not most, but some are used.

Mr. WILES. I think this is an example, if you are driving toward this conclusion, that the dose makes the poison, I think you may have—we all may have trace elements of arsenic, but it is well-known that arsenic is a potent human carcinogen in the wrong doses.

Mr. STENHOLM. And I agree to that and have been very careful in the utilization of arsenic throughout my life.

Ms. HINKLE. Arsenic and old lace.

Mr. STENHOLM. Some of the rest of these, they sound worse. Arsenic doesn't sound so bad, if I didn't know so much about it, but some of these other highfalutin words sound terrible if you did not know you were eating it.

Ms. HINKLE. These were heavy worker exposures and they did cause the kinds of cancers that are cited here, and, therefore, they do prove that there is a cause and effect given sufficient exposure. But we hope that you don't have enough carcinogens in you to create an effect.

Mr. STENHOLM. And maybe I was not coming about this right, but peer review is going to be critical to coming to any scientific conclusion. I think it is going to be extremely important in coming to a political solution; is that we develop a method of having peer review that will have credibility with the general public. And I notice that your heads are shaking affirmatively, at least Mr. Feldman, you were.

This has to be one of our goals. Personally, I have been very encouraged with some of the statements that you have made here today. It goes with Mr. Gunderson's earlier question. I think in some of these areas there is some middle ground. For example, and I want to ask this question, to me it is fairly obvious, but none of you are suggesting that we eliminate all pesticides, herbicides, fertilizers, fungicides, et cetera, from the face of the Earth today.

Ms. HINKLE. No.

Mr. STENHOLM. None of you are. I have not read that, seen that, or heard that in anything you have stated. Sometimes it is inferred, even when you say a goal of 7 years. I believe I am correct in saying that if at the end of that 7-year period there is not a credible alternative, that you would not be in favor of eliminating the ability of our world's farmers to utilize certain pesticides in order

to continue to produce food if there is no alternative within that period. Would you or would you not?

Ms. HINKLE. That is true. I think with a firm deadline you do force technology, since there are companies, as well as public researchers, who know there will be a market by a certain date. So they start the research and development now in anticipation of having a market and then by the time you reach that deadline, you will have the alternatives.

Mr. STENHOLM. What if you don't?

Ms. HINKLE. Well, then you stretch the deadline.

Mr. WILES. We want to be clear we are talking about production alternatives, we are not talking about alternatives measured in terms of economic benefits. We are talking about if there truly are no alternatives to a specific disease of a specific crop, then we would probably favor lengthening of the deadline for phaseout.

Mr. STENHOLM. I apologize to my colleague from Colorado for not recognizing you before I had another round here. Mr. Allard.

Mr. ALLARD. That is all right, Mr. Chairman, you are doing a good job. I did have a question as to how you would, since we are talking about carcinogenic compounds, how would you apply the Delaney clause to arsenic where your standard is zero? And a lot of living organisms have a certain amount of arsenic there. So how do you apply that Delaney clause to arsenic, for example.

Mr. OLSON. Arsenic is an interesting example, because the studies I have seen suggest it is not an animal carcinogen, or at least they don't have an animal model for it yet, but a human carcinogenic—

Mr. ALLARD. It is not an animal—you mean warmblooded animals or it is just a carcinogen—

Mr. OLSON. They have only demonstrated it as a carcinogen through epidemiological studies of humans. They have not identified an animal model yet for it. In other words, the rodent studies have not shown that arsenic causes cancer, at least the ones that I have seen. So that is the flip side.

Mr. ALLARD. Isn't a class A carcinogen—a class A carcinogen, then, is one that causes—pretty well recognized it causes cancer as opposed to a class B or class C?

Mr. WILES. Yes.

Mr. STENHOLM. Would the gentleman yield?

Mr. ALLARD. Yes.

Mr. STENHOLM. This is what gets confusing to a nonscientist, because, Ms. Hinkle, your information that you presented to this subcommittee, Dr. Prescott's "Cancer, The Misguided Cell," states that arsenic compounds, the occupational exposure comes from the metal industry workers, leather workers, painters—people—and the kind of cancer it causes is lung, skin, and liver.

Ms. HINKLE. Lung and skin. That is caused in humans by arsenic. The only kind—

Mr. STENHOLM. It says that it does cause cancer, but yet you were answering Mr. Allard—

Ms. HINKLE. You see, they have discovered it—arsenic as a cause—in human epidemiological studies, then they tried to administer arsenic at even very high doses to laboratory animals. They tried many animals, not only just the standard laboratory animals,

mice and rats, but also other kinds of animals and they have not been able to find one susceptible to arsenic.

However, it says liver here, so, apparently, they did find liver in some other nonhuman.

Mr. OLSON. Some other animal?

Ms. HINKLE. Some other animal.

Mr. STENHOLM. Which is troubling is the way you were answering Mr. Allard. It was troubling to me. And this says that it does cause cancer in humans, or at least some study has suggested that it might.

Ms. HINKLE. No, it did cause cancer. It was found in metal industry workers who worked with arsenic, arsenical compounds, and they had lung and skin cancer. They could conclude the cause and effect because they were exposed to such high levels in their workplace.

Mr. STENHOLM. Not necessarily proven but highly suspected.

Mr. WILES. No, this is a case where the animal models let us down. We would not have known that arsenic is a human carcinogen were it not for the unfortunate situation of these workers. That is what it shows.

Mr. SMITH of Oregon. Would the gentleman yield for just one point?

Mr. ALLARD. Yes, go ahead.

Mr. SMITH of Oregon. I just want to point out there are only two pesticides on this chart and both of them have been abandoned.

Mr. ALLARD. There are three, maybe four possibles on there. But he makes a very good point, though, about those that were listed on here that have been abandoned. This list that you gave us, pretty much industrial exposure compounds, and I don't see any of those being used on food on a regular basis.

But let me go back to your comment about arsenic. We have established, at least generally agreed, that arsenic is causing cancer in humans but it does not cause it in warmblooded animals, laboratory animals in particular. Does the reverse happen? Do we have cancer that occurs in warmblooded animals that does not occur in humans?

Mr. OLSON. It very well may.

Mr. ALLARD. So if that happens, how come it is we always place so much stock in mega doses on laboratory animals as the gospel as to whether it is causing cancer in humans or not?

Mr. OLSON. Because your alternative is to wait until you have bodies of humans stacked up.

Mr. ALLARD. You are overstating that. If that was the case, we would already have them. We would recognize that there is a problem.

Mr. OLSON. Well, that is basically what epidemiology is all about.

Mr. ALLARD. I am familiar with epidemiology.

Mr. OLSON. So, basically, your alternative, you either use animals as your model, accepting there are some vagaries with that approach, or you wait until humans get the cancer and then you count up and figure out whether you have a large enough effect to document through an epi study that the cancer has occurred.

It is our view that a preventive health approach is to use the animal studies and recognize, of course, that they are not perfect and

that you may get some false positives. You may also, like in arsenic, get some false negatives.

Mr. ALLARD. So in view of that, does the Delaney clause make much sense to you, then? Doesn't a policy of negligible risk make more sense? It is based on science, it is based on probability, and not based on an absolute figure that has nothing to do with health risk?

Mr. OLSON. I think the Delaney clause, the fundamental policy statement in the Delaney clause, which is that we should not intentionally add a carcinogen to the food supply, makes sense.

The question is, you raise a question of how you implement that fundamental policy. There is a policy question here which is often muddled with scientific questions. The policy question is should we or should we not intentionally add carcinogens to the food supply? That is the kind of policy question Congress is equipped to answer.

Mr. ALLARD. You think policy questions should be based on science?

Mr. OLSON. Of course. And the scientific question, as I was about to say, is—

Mr. ALLARD. So how do we distinguish between policy questions and scientific policy? Several members of this panel have made comments in the past that you are trying to differentiate between scientific policy and policy questions, and I don't know why you should try to differentiate.

I think you have to recognize that science is not perfect and that there is some practical aspects to approaching this problem. You should not carry the solution to the extreme that you forget about what your goals are, which is public health. And so it seems to me that you have to carry some sort of a concept of negligible risk.

Mr. OLSON. Well, the policy question is, do you want to intentionally add the carcinogens? If you say yes, I want to add some carcinogens as long as the risk is negligible, then the next question is, how do you define negligible. If you know that one person is going to die in the United States next year, is that acceptable? If you know that 10 people are going to die next year, is that acceptable? If it is 1,000 people, is that acceptable?

Mr. ALLARD. Is that acceptable to what?

I serve on the Foreign Agriculture and Hunger Subcommittee, and we had an expert here talk about agricultural production who says, he can recall not far back we had the predictions that people were beginning to die because of starvation and whatnot 20 years ago, but he says the one thing that turned all these dire predictions around and why we don't have people starving today is because of the technical scientific advancement that has occurred in agriculture. I said, would you be more specific. He says because we have developed fertilizers, because we have developed pesticides.

So sometimes the choice may be malnutrition, where you have an adequate supply of food, or it might be starvation. There might be 1,000 people that may have died from insecticides, but if you have 10,000 people dying from starvation, I think if you are a responsible party that you address the 10,000-person problem because that is where most of your deaths are occurring.

That is the type of decision a physician will make every day as to whether the product that he is giving, whether it is a drug or

whatever, whether the side effects are greater than the benefits of the product. And I think we have to look at that from the policy here, whether the side effects are more detrimental than the benefit to be derived.

Further testimony we had was on vitamin A deficiency and what a huge problem we have worldwide on high vitamin A deficiency, yet we need to have adequate amounts of vegetables available to people to eat for vitamin A so they don't die.

It seems to me you need to have some type of chemical available to create the proper balance so that you have healthy people because they are eating healthy food, and it may mean, in certain instances, you have to have an insecticide or fertilizer to do that.

Mr. OLSON. I guess what we are saying is not inconsistent with that. What we have repeatedly said is you give time to phase out the pesticides that are causing the problems. We believe that if you give—

Mr. ALLARD. Give us some pesticides now that are carcinogens that we are using on food.

Mr. OLSON. Atrazine.

Mr. ALLARD. Atrazine is not used routinely on foods.

Mr. OLSON. Sure, it is.

Mr. ALLARD. It is used routinely?

Mr. FELDMAN. Yes.

Mr. OLSON. There are plenty, if you look at the examples—

Mr. ALLARD. Is it applied directly? It is not applied directly to food, is it?

Mr. OLSON. It is applied to—

Mr. ALLARD. It is a herbicide applied to—

Mr. OLSON. Corn, among others.

Mr. ALLARD. Wheat, but before the corn comes up.

Mr. OLSON. It is not just a preemergence herbicide.

What we are saying is there are about, EPA has listed approximately 30, and when I said atrazine is a carcinogen, what I was referring to is EPA's categorization. There are several categorizations. There are some that are B's, some C's. I believe atrazine I believe is a C.

Mr. OLSON. It is a C, I believe.

Mr. ALLARD. So it is a possible, not confirmed?

Mr. OLSON. That is right.

Mr. ALLARD. No, I am asking, those that are—give me a class A pesticide that is being used directly on food.

Mr. WILES. I don't think there are any right now but there are—

Mr. OLSON. Most of those chemicals have been phased out.

Mr. ALLARD. You see, I think we are moving forward on this issue and I think we are trying to accomplish that, then we get into the class B's that are probables and then we get into class C's that are suspect but certainly have not been established and atrazine is a class C.

And so now in your testimony we don't have any class A's that are established carcinogens that are being used directly on food routinely. Do we have any B's?

Ms. HINKLE. Yes.

Mr. WILES. Yes.

Mr. ALLARD. How many B's do we have?

Mr. WILES. About 25 or 30. We have a list that we have developed. I don't have it with me.

Mr. ALLARD. It would be helpful. Because when I look at this list here that was given to us from Ms. Hinkle, as the colleague from Oregon pointed out, those are no longer available on the market. Carbon tetrachloride was one which is no longer available as far as pesticides are concerned. Ethylene dichloride was the other. There is an organochloride pesticide, but and I am not very familiar with it. There is organic phosphates but organochloride, I don't know that that has been used on food.

Then you have arsenical compounds on the left but these are mainly industrial exposures much minor than what you get on food.

Ms. HINKLE. Lindane would be an organochloride.

Mr. ALLARD. It is off the market?

Ms. HINKLE. No, it is still on the market, and cadmium is still used.

Mr. ALLARD. Lindane is still on the market? For what? It cannot be used on animals. It has been taken off for animals.

Ms. HINKLE. Seed treatment.

Mr. ALLARD. On seed treatment?

Ms. HINKLE. Jay Vroom should know.

Mr. FELDMAN. It is also on rice treatment?

Mr. ALLARD. The classification—is lindane, then, a class B or C?

Ms. HINKLE. It is a B.

Mr. ALLARD. It is one of the B's.

Ms. HINKLE. I am being coached.

Mr. WILES. I can name you B's, if you want.

Mr. ALLARD. The point is, we don't have any confirmed carcinogens today that are being used on food on a routine basis.

Ms. HINKLE. Oh.

Mr. WILES. Is that A's?

Mr. ALLARD. Yes.

Mr. WILES. No, and that is good.

Mr. ALLARD. I think it is good too. I think it shows progress. I think that we are moving ahead, and so that we have had—there was this concern about the fact that the National Academy of Sciences was saying—I guess you were quoting the National Academy of Sciences or saying that you felt like we needed to do more in trying to control insecticides. And current laws we had did not give us the power to control a lot of problems we had with insecticides, and it seems to me that we are addressing it.

Mr. WILES. We don't think we have made sufficient progress and we think the law allows too high a level of risk and we think we need specific consideration and safety protection standards for children in the law so that the Administrators are not forced to make decisions on a case-by-case basis.

We think we need to move American agriculture away from the current use of carcinogenic compounds in a reasonable way.

Mr. ALLARD. So your testimony is we don't have any compounds on the market correctly applied to food that causes cancer, class A's?

Mr. WILES. That are proven human carcinogens, right.

Mr. ALLARD. That is a class A. Now you are saying we are not doing enough and I agree we can get better.

Mr. WILES. Probable human carcinogens cause cancer in two species, both sexes, typically at multiple sites in a strong dose response fashion, and we think that that is enough. If they are categorized as probable human carcinogens, I don't think as a matter of public policy we should wait to prove that they are causing cancer before we remove them from the food supply, particularly when we have many other chemical alternatives that are noncarcinogen and when noncarcinogenic—and when through a good research program, we could move farmers away from dependence on these compounds in the first place.

Mr. FELDMAN. The basis—could I say the basis of the policy that we are dealing with is attaching some meaning to those laboratory studies in animals. That is the basis even in H.R. 1627. The basis of using animal studies to determine carcinogenicity is not challenged by this bill. It still relies on the current rating of carcinogenicity. The question is, what do you think we should do as a matter of policy once we get that information on carcinogenicity?

I urge you to take a look at this study that was put out here. I cite on page 6 of my testimony, footnote 7, I can get you a copy of it, in which the International Agency for Research on Cancer reviewed data on 44 known human carcinogens, most of which are industrial carcinogens, and went back and looked at the animal data and found in over 80 percent of the cases the laboratory animal data showed cancer. And in the 20 or so percent cases where it wasn't shown, the laboratory studies were not adequate. They were not finished, completed, or there was something wrong with them.

So we have a pretty good track record in terms of using these animal studies to show what the effect will be in the human population. And I don't think we should dismiss it, and H.R. 1627 does not dismiss it either. It acknowledges or it accepts at least the method by which we now determine carcinogenicity.

Ms. HINKLE. The National Cancer Institute has underway studies of cancer in farmers, and they have been undertaking these cluster studies for about the last 4 years, and there is concern about the statistically significant increase in certain kinds of cancer related to certain kinds of farming.

So it would seem to be prudent public policy to reduce the kinds of carcinogenic pesticides that are used widely, and if we can find alternatives, then I think we should be willing to do that.

Mr. ALLARD. It is interesting to see how that study comes out in different classes of farmers. In public health epidemiology, there is a higher incidence of cancer in urban areas than rural areas.

Ms. HINKLE. Apparently, farmers were selected because they are very healthy and ought not to be disposed toward cancers. The studies have proven to be worrisome, and I can get them to you, if you like.

Mr. ALLARD. Thank you.

Thank you, Mr. Chairman.

[The information follows:]

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August 11, 1993

The Honorable Charles Stenholm
Chairman
Subcommittee on Department
Operations and Nutrition
Committee on Agriculture
U.S. House of Representatives
Washington, D.C. 20515

Dear Mr. Chairman:

This letter is respectfully submitted for the record of the hearing you chaired on Monday, August 2, 1993. The first witness of the fourth panel, Mr. Jay Vroom, questioned the percent of pesticides that I claimed, in response to questions, to have been classified as carcinogens. I would like to set the record straight in that regard. I have also attached, for the record, a summary of studies conducted by the National Cancer Institute in response to the questions raised by Representative Wayne Allard about epidemiological studies of cancer incidence in farmers.

According to the National Academy of Sciences 1987 Study, *Regulating Pesticides in Food -- The Delaney Paradox*, "on the basis of pounds of pesticide applied, 60 percent of all herbicides are oncogenic or potentially oncogenic. . . By volume, 90 percent of all fungicides fall into this category, as do about 30 percent of all insecticides." This is from pages 4-5 of that Report.

I hope that this information is helpful to the subcommittee. If you have any further questions or need for information, please let me know.

Sincerely yours,

Maureen Kuwano Hinkle
Director, Agricultural Policy

Enclosure: Summary of recent NCI studies of cancer among farmers

National Cancer Institute Studies

Agricultural Herbicide Use and Risk of Lymphoma and Soft-Tissue Sarcoma. Sheila K. Hoar, ScD, Aaron Blair, Frederick F. Holmes, Cathy D. Boysen, Robert J. Robel, Robert Hoover, Joseph F. Fraumeni, Jr.; Journal of the American Medical Association; Volume 256; September 5, 1986.

Farm herbicide use, especially phenoxyacetic acids, found to be associated with non-Hodgkin's lymphoma (NHL).

Cancer Among Farmers. Aaron Blair, pd, Sheila Hoar Zahm, ScD; Occupational Medicine: State of the Art Reviews; Volume 6, No. 3; July-September 1991.

Combined surveys from many countries have found that farmers have elevated risks for certain malignancies. Attempts to identify specific agents in the agricultural environment that might account for such excesses among farmers have only recently begun.

Cancer Mortality in the U.S. Flour Industry. Michael C.R. Alavanja, Aaron Blair, Mary N. Masters; Journal of the National Cancer Institute; March 6, 1990.

Studies found workers employed in flour mills, where pesticides are used more frequently than in other segments of the industry, were found to have excess risks for developing non-Hodgkins lymphoma, leukemia, and pancreatic cancer.

A Case-Control Study of Non-Hodgkin's Lymphoma and the Herbicide 2,4 - Dichlorophenoxyacetic Acid (2,4 - D) in Eastern Nebraska. Sheila Hoar Zahm, et al; Epidemiology; Volume 1, No. 5; September 1990.

The risk of NHL among men increased with the average frequency of use and degree of exposure to 2,4 - D.

A Case Referent Study of Soft-Tissue Sarcoma and Hodgkin's Disease. Sheila K. Hoar, et al; JAMA; Volume 256, No. 9; September 5, 1986

Multi-national reports indicate that persons exposed to phenoxyacetic herbicides and chlorophenol have up to a sixfold excess risk of soft-tissue sarcoma, Hodgkin's disease, and non-Hodgkin's lymphoma.

Clues to Cancer Etiology From Studies of Farmers. Aaron Blair, et al. Scand J Work Environmental Health; Volume 18; 1992.

Summarizes cancer risks among farmers and suggests epidemiologic studies on specific exposures among farmers.

Comparability of Data Obtained From Farmers and Surrogate Respondents on Use of Agricultural Pesticides. Linda Morris Brown, Mustafa Dosemeci, Aaron Blair, and Leon Burmeister; American Journal of Epidemiology; Volume 134, No. 4; April 1, 1991.

Responses from spouses, or other surrogates, appear to be adequate for epidemiologic studies of pesticides and cancer.

Pesticides and Cancer. Robert N. Hoover, Aaron Blair; Cancer Prevention; February, 1991.

General report on hazardous effects of pesticides, particularly carcinogenicity.

Methodologic Issues in Exposures Assessment for Case-Control Studies of Cancer and Herbicides. Aaron Blair, Sheila Hoar Zahm; *American Journal of Industrial Medicine*; Volume 18; 1990.

Epidemiologic studies of cancer and exposure to herbicides have shown puzzling inconsistencies, and procedures for such testing are examined.

Pesticide Exposures and Other Agricultural Risk Factors for Leukemia Among Men in Iowa and Minnesota. Linda Morris Brown, et al; Cancer Research; Volume 50; October 15, 1993.

Investigation of association between leukemia and farming led to finding of elevated risks for insecticides used on animals.

Pesticides and Other Agricultural Risk Factors for Non-Hodgkin's Lymphoma Among Men in Iowa and Minnesota. Kenneth P. Cantor, et al; Cancer Research; Volume 52; May 1, 1992.

The consistency of several findings suggests an important role for numerous insecticides in the etiology of non-Hodgkin's lymphoma among farmers.

Mr. STENHOLM. I thank all of the witnesses. This has been a very helpful panel today. I believe that you would concur that the messenger was not shot.

Ms. HINKLE. Only tortured.

Mr. STENHOLM. We sincerely look forward to working with you as we resolve some very difficult questions.

And, for the record, to those who may not be aware of it, Mr. Alard does have a little bit of background in the subject of which we are talking about. But, even more importantly, he happens, in a sense, in the spirit of peer review and scientific peer review, and who happens to be who in the public health sector, he happens to be the family doctor for at least four members of this subcommittee.

Ms. HINKLE. I thought he was a veterinarian.

Mr. STENHOLM. Thank you very much for being here with us today.

I will call panel 4. Mr. Jay Vroom, president, National Agricultural Chemical Association; Warren Stickle, president, Chemical Producers and Distributors Association; accompanied by William Gullickson, chairman of the board, Chemical Producers and Distributors Association; Ralph Engel, president, Chemical Specialties Manufacturers Association; Gerald R. Pflug, president, the Soap and Detergent Association; accompanied by Dennis C. Griesing, director, public affairs, the Soap and Detergent Association; Jerry Johnston, president, Johnston Fertilizer, representing Agricultural Retailers Association; accompanied by Chris Myrick, director, regulatory/legislative affairs, Agricultural Retailers Association; and Thomas Diederich, vice president, government relations, Orkin Pest Control and Lawn Care, and chairman, Government Affairs Committee, National Pest Control Association,

We will ask each of you to hold your testimony to 5 minutes. Your statements will be made a part of the record.

The first witness is Mr. Jay Vroom, president, National Agricultural Chemicals Association.

STATEMENT OF JAY J. VROOM, PRESIDENT, NATIONAL AGRICULTURAL CHEMICALS ASSOCIATION

Mr. VROOM. Thank you, Mr. Chairman and members of the subcommittee. Thank you for allowing us to go last. It is good discipline for us to be here and listen to the other testimony and your questions and the answers that come back.

I would like to say, going back to the last hearing that you conducted and the questions that you posed to many of us who are assembled here today representing the industry, that you wondered if we had any contact with the environmental community, a panel much the same as the one just preceding us. I think we universally said no. I have been attempting to talk to some of our friends in the environmental community and will continue to try to do so.

I will continue to try to talk to Maureen Hinkle about her statement that proceeded us where she said she knew definitively that 95 percent of the pesticides are carcinogens. I know of nothing on the public record to support that. Perhaps we will be able to share that information with you.

The world is a very complicated place. There are many vexing issues of a complex nature like the Delaney reform in front of us. Seldom do we have such clear choices to make as the differences between the Lehman-Bliley bill and the Kennedy-Waxman approach.

I thought I would concentrate on a couple of those at the beginning. First, H.R. 1627 continues to allow consideration of benefits, we believe, to consumers and from the safe use of crop protection products; while Kennedy-Waxman is looking only at risks and turning a blind eye at things that should also be measured.

On the risk front, the Lehman-Bliley approach does not use a bright line, 1 in 1-million standard, followed with an additional very specific narrative that would dictate many classes of essential crop protection products and food combinations. This is a legislative vehicle that provides progress.

It further protects health and encourages a stronger and better American agriculture through positive incremental steps.

Kennedy-Waxman would serve to dismantle America's agricultural system and would likely increase a myriad of risks to consumers.

There are a number of improvements that we have suggested in our written testimony. Five of those include speeding the cancellation process prescribed in H.R. 1627. We in NACA recommend that an absolute 1 year deadline be placed on the cancellation process.

Another idea that we suggest be further pursued, perhaps using Chairman de la Garza's approach to the benefit of agricultural growers as well as very important nonagricultural, specialty pesticide users, NACA is very concerned about the minor-use crisis from the perspective of the right-of-way maintenance, and structural pest control.

We have also suggested in our written statement benefits consideration.

And, finally, we encourage you to consider the issue of preemption of local pesticide regulation with the Federal-State partnership approach using the coalition for a sensible pesticide policy approach which was reported out of the old DORFA subcommittee last year.

There are a number of repairs that are under consideration at EPA, and in the context of what you are trying to do with the legislative approach most of those fall under the guise of it.

Policy and coordination of policy have already been discussed. We also call attention to the questions that have been widely discussed this afternoon relating to the definition of what produces cancer and also the MTD policy question.

Finally, we want to say that diets of infants and children are an important and wide-ranging new aspect of public confidence overall.

We at NACA and all of our member companies have widely heralded the report of the National Academy of Sciences and many of its recommendations. However, we do want to bring to the attention of the subcommittee one misrepresentation in the report where it is construed that the report says tolerances are based only on agricultural considerations, when, in fact, members of my association spend hundreds of millions of dollars testing the health aspects of our compounds.

The report incorrectly leads the reader to believe that only agricultural concerns are used to develop legal pesticide residue tolerances. That is not true.

We thank you. We hope you move H.R. 1627 forward, and we look forward to working with you.

[The prepared statement of Mr. Vroom appears at the conclusion of the hearing.]

Mr. STENHOLM. Mr. Warren Stickle, president, Chemical Producers and Distributors Association.

STATEMENT OF WARREN E. STICKLE, PRESIDENT, CHEMICAL PRODUCERS AND DISTRIBUTORS ASSOCIATION, ACCOMPANIED BY WILLIAM D. GULLICKSON, JR., CHAIRMAN OF THE BOARD

Mr. STICKLE. My name is Warren Stickle. Today, I am accompanied by Bill Gullickson, president of the McLaughlin, Gormley King Company and chairman of the Chemical Producers and Distributors Association.

I would like to commend you and the subcommittee for the efforts that you have made over the last 2 months in bringing forth a series of hearings on FIFRA. Your efforts, I think, have gone a long way to raising the level of awareness with regard to the complexity of trying to regulate pesticides.

I would at this time like to ask Bill Gullickson to comment on H.R. 1627.

Mr. STENHOLM. Mr. Gullickson, please proceed.

Mr. GULLICKSON. Thank you, Mr. Chairman.

Before I start my remarks, I would like to commend this committee for the work that you have done on the flood relief efforts. As a citizen of Minnesota, we also appreciate your efforts, as did a prior witness from Illinois.

We are here to talk. We are here, of course, to discuss H.R. 1627 and, in particular, the provisions of the bill which deal with cancellation and suspension under FIFRA, the concept of negligible risk in setting tolerances for pesticide residues in foods under the Federal Food, Drug, and Cosmetic Act, FIFRA, and the definition of a pesticide.

I would also like to discuss several related issues. These include a set of recommendations for the expedited review of "me-too" pesticide registrations and simple label amendments—commonly referred to as fast track, the need for label reform within EPA and the need to preserve an important class of pesticides utilized in public health programs.

We at CPDA strongly support H.R. 1627, the Food Quality Protection Act of 1993. The bill would create a single negligible-risk standard for tolerances for pesticide residues in raw commodities and processed food.

The zero risk Delaney standard is simply unworkable for establishing reasonable risk evaluation. When Delaney was promulgated almost 35 years ago, the usual scientific testing standards measured in the parts per million. Scientific detection standards now measure in the parts per trillion and greater, resulting in the detection of carcinogens which present, at the most, a remote and negligible threat to the public.

During the continuing discussion about the need for food safety reform, the process and procedures by which the Environmental Protection Agency cancels or suspends a product is at the heart of the need to revamp our pesticide regulatory program.

We support the Environmental Protection Agency's need to move quickly to remove problem pesticides from the marketplace.

We also agree that the experience of the last 15 years has clearly demonstrated that the cancellation process has taken too long.

We strongly support the cancellation provisions of H.R. 1627.

We strongly support the suspension provisions in section 104 of H.R. 1627. We believe that there is no need to change the suspension provisions of FIFRA, since no one has clearly demonstrated that the current suspension authority has not worked. In fact, suspension authority has only been utilized three times in the last 20 years.

Other factors such as the escalating data requirements, the considerable care in registering products, the comprehensive reregistration of all products, including old chemicals, and the use of means short of suspension are really working.

We strongly support title II of H.R. 1627 that establishes procedures for the collection of pesticide use information.

The USDA is to be commended for its new data collections program it has undertaken during the last 3 years.

Rather than making assumption about residue levels, based upon pesticide applications, we are able to obtain a more realistic account of the actual residues, if any, that are on the fruits and vegetables. The closer we get to the grocery store, the more accurate and realistic statistics we can gather.

Also, we strongly support the Integrated Pest Management, IPM, provisions of title II, section 202, that encourages the EPA and USDA to research, develop, and disseminate integrated pest management techniques.

In addition, we also support the international harmonization provisions of title III, section 305(j), which would require the EPA to take into account the CODEX recommended international residue limits, MRLS, and to explain any departure from the CODEX limits.

Last, we strongly support the provisions of the national uniformity of tolerances as contained in section 305(l). We cannot promote interstate commerce in food products if we allow 50 states and 83,000 local political subdivisions to establish their own tolerance levels.

Although we strongly support H.R. 1627, we have some real concerns about shifts in the definition of a pesticide chemical and a pesticide chemical residue as contained in section 302(a) of title III—Amendments to the Federal Food, Drug, and Cosmetic Act.

As presently written in H.R. 1627, a pesticide chemical residue is defined as a residue of a pesticide chemical, including its active ingredients and inert ingredients. Under present FIFRA, inert ingredients are not included in this definition. Thus, if the language is adopted, we would establish one definition of a pesticide which EPA uses under FIFRA and another expanded definition for use by FDA under FFDCA.

We at CPDA greatly appreciate this subcommittee's efforts to hold this hearing on important FIFRA issues. We strongly support H.R. 1867, the Food Quality Protection Act of 1993, for its treatment of Delaney as well as its provisions regarding cancellation, suspension, data collection, IPM, international harmonization, and national uniformity of tolerances.

We do, however, believe that the definition of a pesticide chemical as currently written in the bill needs to be changed to delete inerts.

We applaud the subcommittee for its leadership on pesticide issues and look forward to working with you during the 103d Congress.

[The prepared statement of Mr. Gullickson appears at the conclusion of the hearing.]

Mr. STENHOLM. I believe, if it meets with your approval—we have three additional witnesses. If you could hold your remarks to 3 minutes, we can let you go. We are going to have a series of votes. We will wind this up and come back again another day.

STATEMENT OF GERALD R. PFLUG, PRESIDENT, SOAP AND DETERGENT ASSOCIATION, ACCOMPANIED BY DENNIS C. GRIESING, DIRECTOR, PUBLIC AFFAIRS

Mr. PFLUG. Mr. Chairman and members of the subcommittee, my name is Gerald Pflug. I am president of the Soap and Detergent Association.

The Soap and Detergent Association is a 139-member national trade association representing the formulators of soaps, detergents, and household cleaning products and those companies which supply ingredients to the detergent and cleaning products industry.

I am here today on behalf of SDA's antimicrobial/disinfectant products sector because this beneficial category of products faces a number of regulatory problems which we believe ought to be addressed through reform of the FIFRA process.

The principal problems of concern are the following:

The prolonged time it takes to get a new compound approved. As we mentioned in our previous testimony here, there have been no new antimicrobial products approved in the last 7 years.

The process for registering or reregistering products is so cumbersome and attenuated that such processing may require up to 2 years to complete. Approval of simple label changes may take 9 months or more.

It seems to us that establishment of a separate regulatory track would benefit the EPA as well as the industry by clarifying standards and establishing, in effect, a division of labor in the FIFRA regulatory approval process.

SDA realizes the enormous task currently being undertaken by EPA in the reregistration of pesticides. We also recognize that the agency operates, as do all human enterprises, with finite resources. However, the agency also has a responsibility to see that all its various regulated communities, communities whose ability to conduct business depends on the agency, receive equitable allocations of regulatory resources. While priorities may need to be assigned, that assignment ought not to unduly encumber the ability of other agency-dependent, regulated industries to conduct business.

The Food Quality Protection Act of 1993, H.R. 1627, deals with extremely important issues. My purpose in being here today is to urge you not to lose sight of other FIFRA-related matters which, while perhaps more mundane by comparison, are deserving of your attention in the development of FIFRA-related legislation.

While I wish that I could offer you a comprehensive solution to the issues of our concern, I cannot do so today. I am pleased to tell you, however, that the SDA is currently working to develop a more concrete proposal for your consideration along with allied associations. We are hopeful that our proposal will be available in the very near future.

Mr. Chairman and members of the subcommittee, this concludes my formal remarks. The SDA appreciates the opportunity to be here today, and I would be pleased to answer any questions you might have at this time. Thank you.

[The prepared statement of Mr. Pflug appears at the conclusion of the hearing.]

Mr. STENHOLM. I assure you we will not offer all of what you would call the unusual aspects of this legislation.

The next witness is Mr. Engel.

STATEMENT OF RALPH ENGEL, PRESIDENT, CHEMICAL SPECIALTIES MANUFACTURERS ASSOCIATION

Mr. ENGEL. Good afternoon, Mr. Chairman. Good afternoon to the subcommittee members as well.

My name is Ralph Engel. I am president of the Chemical Specialties Manufacturers Association, CSMA. CSMA represents the non-agricultural pesticide industry, including disinfectants and sanitizers, alone or together with cleaning compounds. These are for home, industrial, and institutional use.

While the vast majority of CSMA members do not produce products used on food, feed, or fiber crops, we do recognize the need for Congress to enact comprehensive food safety legislation which both resolves the Delaney paradox and appropriately streamlines FIFRA's cancellation and suspension procedures. The Lehman/Bliley legislation, H.R. 1627, is clearly the most serious and balanced effort to accomplish those goals under consideration in the 103d Congress. That is why it has attracted more than 100 bipartisan cosponsors. CSMA supports the Lehman/Bliley legislation.

The ninth circuit court of appeals decision in *Les v. Reilly*, 968 F.2d 985, ninth circuit, 1992, has reemphasized the need for Congress to enact a negligible risk standard for establishing legal pesticide residues in food. A zero-risk standard, as required by the *Les* decision, would significantly limit the availability of pesticidal products which offer substantial benefits to society without threatening the public health.

Overly restrictive definitions of negligible risk as proposed by Representative Waxman, H.R. 872, are equally troublesome. CSMA supports a negligible risk standard consistent with present risk ranges— 1×10^{-5} to 1×10^{-6} —used by EPA, FDA, and other Federal agencies. The risk assessment process used by EPA in setting tolerances should not be prescribed in statute, as is done in H.R. 872. EPA should instead be provided with appropriate scientific flexibil-

ity and discretion, as is contemplated by the Lehman/Bliley narrative negligible risk standard.

Over the past few years, EPA has expressed concern over what it considers to be the cumbersome and time-consuming process required to cancel or suspend a registration. CSMA understands the Agency's concern and believes it should be provided the tools to promptly address pesticides which pose an unreasonable adverse effect to human health or the environment as established by sound science. Those reforms should be balanced by the preservation of appropriate due process protections as are proposed in H.R. 1627. Our goal should be to ensure an adequate chance for rebuttal by the registrants as well as a proper forum for consideration of all relevant factors for cancellation or suspension of a pesticide. CSMA will continue to objectively look at any reasonable proposal offered by EPA and others concerning this issue but remains committed to maintaining appropriate procedural safeguards in the cancellation and suspension process.

Mr. Chairman, your decision to focus your first FIFRA hearings 2 months ago on the problems plaguing the EPA pesticide registration program has served to bring to the forefront the cumbersome and anticompetitive registration process and the widespread dissatisfaction with the program's performance. Representatives of the agricultural and nonagricultural chemical, biotechnology, cleaning, and antimicrobial industries all expressed serious concerns about the program's ability to meet congressional mandates for registration of pesticides. The registration process is not working, and EPA must be held accountable and be specifically directed to immediately institute procedures to unclog the system.

During the June 8 hearing, you concurred with an idea put forward by the Chemical Specialties Manufacturers Association and supported by others that an independent external examination of the Office of Pesticide Programs, OPP, and the entire registration and reregistration program is in order. We urge that such an effort be undertaken promptly and that a report to Congress with specific recommendations for improved program performance be available for review at the start of the 1994 congressional session.

I will ask that my statement be placed in the record in full.

I would like to make some comments about previous statements, if I may.

[The prepared statement of Mr. Engel appears at the conclusion of the hearing.]

Mr. STENHOLM. We have to go vote. Maybe we can take one more statement.

Mr. MYRICK. Mr. Johnston has to catch a plane.

Mr. STENHOLM. OK, Mr. Johnston.

**STATEMENT OF JERRY JOHNSTON, GENERAL MANAGER,
JOHNSTON FERTILIZER, ROBSTOWN, TX, ON BEHALF OF THE
AGRICULTURAL RETAILERS ASSOCIATION, ACCOMPANIED
BY CHRIS MYRICK, DIRECTOR, REGULATORY/LEGISLATIVE
AFFAIRS**

Mr. JOHNSTON. Mr. Chairman, I thank you for allowing me to testify on behalf of the 6,000 retail outlet members of the Agricultural Retailers Association or ARA.

I am general manager for Johnston Fertilizer, Robstown, Texas. Johnston Fertilizer services 150 farmers growing cotton, grain sorghum, corn, and ranchers with coastal Bermuda grass with liquid fertilizer and crop protection chemicals.

I wish to commend this subcommittee for its efforts to move the food safety issue and FIFRA reauthorization forward. As you will see in my testimony, the U.S. agricultural industry now faces a critical moment in its history. Should we lose the benefits of crop protection chemicals and the ability to register new products because of overly stringent food safety laws, the future of America's abundant and safe food supply will be put in jeopardy.

Without the passage of H.R. 1627 we will continue to see the loss of minor-use products and general-use pesticides in the near future. Further, new products will almost be impossible to register if H.R. 1627 is not adopted.

As you will see in my written statement, ARA suggests only minor changes in H.R. 1627.

ARA believes that it is also important for this subcommittee to take into consideration our suggestions for amending FIFRA which are not contained in this bill.

Already, the subcommittee has heard calls for expanded record-keeping and other recordkeeping programs which will directly impact my business and the business of my producer customers. Considering the economic impact your decisions are having on our industry, it is important that their impact not be overlooked.

ARA estimates regulatory compliance costs for retail dealers will increase by 300 percent by 1993 and the industry will lose 30 percent of its dealers by the year 2000.

I have attached a listing of current regulatory requirements and costs with my written statement.

Now to move on to other specific suggestions, ARA is opposed to expanded recordkeeping and reporting for pesticidal reports beyond those that are currently imposed.

We also expect that this committee will hear requests to expand current applicant or certification and training requirements. ARA believes that legislative expansion, certification and training is not necessary because of existing EPA authority. In fact, EPA has already issued an order which is expected to become final later this year.

Look at preemption of address as part of FIFRA reorganization. This is a confusing set of pesticide laws that are impossible for dealers of custom-applied products to meet. For example, I custom apply products in several Texas jurisdictions and local townships. If each of these jurisdictions creates a separate set of unique laws on top of the already numerous State and Federal laws that we have to comply with, I might as well just close my doors.

This concludes my testimony.

[The prepared statement of Mr. Johnston appears at the conclusion of the hearing.]

Mr. STENHOLM. I apologize. Mr. Diederich.

Mr. DIEDERICH. We would like to thank you for the opportunity to appear. We have a statement for the record.

[The prepared statement of Mr. Diederich appears at the conclusion of the hearing.]

Mr. STENHOLM. We must leave now to vote.

The subcommittee is adjourned.

[Whereupon, at 4:30 p.m., the subcommittee was adjourned, to reconvene, subject to the call of the Chair.]

[Material submitted for inclusion in the record follows:]

TESTIMONY BY CONGRESSMAN RICHARD LEHMAN
BEFORE
THE HOUSE AGRICULTURE SUBCOMMITTEE ON
DEPARTMENT OPERATIONS AND NUTRITION
REGARDING
H.R. 1627, THE FOOD QUALITY PROTECTION ACT OF 1993

August 2, 1993

Washington, DC

MR. CHAIRMAN: I WANT TO THANK YOU AND YOUR COLLEAGUES ON THE SUBCOMMITTEE FOR TAKING THIS LEGISLATION UNDER CONSIDERATION. I AND CONGRESSMEN BLILEY AND ROWLAND STRONGLY BELIEVE THAT THIS MEASURE IS THE BEST APPROACH FOR NEEDED REFORM OF OUR FOOD SAFETY LAWS. WE APPRECIATE THIS OPPORTUNITY TO PRESENT OUR LEGISLATION AND EXPLAIN THE MERITS OF OUR APPROACH TO THIS ISSUE.

WHILE I UNDERSTAND THAT THE AGRICULTURE COMMITTEE ONLY HAS JURISDICTION OVER THE PART OF THE BILL WHICH DEALS WITH PESTICIDE REFORM, WE CAN NOT FORGET THAT THIS ISSUE IS IRREVERSIBLY LINKED TO FOOD SAFETY REFORM. WE CAN NOT TELL OUR FARMERS THAT A CERTAIN PESTICIDE IS SAFE TO APPLY TO CROPS BUT NOT SAFE ENOUGH IF ANY OF ITS RESIDUE IS LEFT ON THE PRODUCT BEING SENT TO BE PROCESSED.

THE RECENT STUDY BY THE NATIONAL ACADEMY OF SCIENCES ON PESTICIDES AND CHILDREN HAS HIGHLIGHTED THE NEED FOR UPDATED FOOD SAFETY LEGISLATION. WHILE THE UNITED STATES HAS SOME OF THE HIGHEST SAFETY STANDARDS AND LOWEST FOOD PRICES IN THE WORLD, THERE IS ALWAYS ROOM FOR IMPROVEMENT. THIS STUDY AND A RECENT CIRCUIT COURT DECISION UPHOLDING THE "DELANEY CLAUSE" DEMONSTRATE HOW EASILY OUTDATED OUR FOOD SAFETY STANDARDS CAN BECOME.

AS YOU KNOW, A 1950'S AMENDMENT TO THE 1938 FEDERAL FOOD, DRUG, AND COSMETIC ACT (FFDCA) KNOWN AS THE "DELANEY CLAUSE" ALLOWS CERTAIN PESTICIDES TO BE USED ON RAW FOODS BUT NOT ON PROCESSED FOODS. IN OTHER WORDS, WHAT IS SAFE FOR AN APPLE IS NOT SAFE FOR APPLE SAUCE. EPA, IN IT'S ENFORCEMENT OF THESE DIVERGENT STANDARDS, HAS FLEXIBLY INTERPRETED THE STANDARD FOR PROCESSED FOODS TO ALLOW FOR A "NEGLIGIBLE RISK" RATHER THAN A "ZERO RISK" TO HUMAN HEALTH.

DUE TO MODERN SCIENCE, EVEN THE MINUTEST DEGREE OF A POTENTIALLY CANCER CAUSING RESIDUE CAN BE DETECTED IN FOODS. IF THE STRICT INTERPRETATION OF THE DELANEY CLAUSE'S "ZERO RISK" STANDARD IS APPLIED, THEN MANY SAFE AND EFFECTIVE PESTICIDES WHICH ENSURE A PEST-FREE, HARMLESS FOOD SUPPLY WOULD BE PROHIBITED.

UNFORTUNATELY, BECAUSE THE NINTH CIRCUIT COURT HAS TAKEN AWAY EPA'S DISCRETION TO USE A "NEGLIGIBLE RISK" STANDARD, THIS IS EXACTLY WHAT IS HAPPENING. EPA HAS THREATENED TO BAN 35 INVALUABLE, WIDELY USED PESTICIDES THAT WOULD LEAVE A HARMLESS BUT TRACEABLE AMOUNT OF RESIDUE IN PROCESSED FOODS.

AS A REPRESENTATIVE FROM THE CENTRAL VALLEY OF CALIFORNIA, THE RICHEST FOOD PRODUCTION AREA IN THE COUNTRY, I SHARE THE CONCERN OF THE GROWERS IN MY DISTRICT THAT THE UNCERTAINTY CREATED BY THESE DEVELOPMENTS MAY SEVERELY ALTER THE FRAMEWORK OF AMERICAN AGRICULTURE. THE LOSS OF USEFUL PESTICIDES WILL LEAD TO A LOSS OF VALUABLE CROPS, MANY UNIQUE TO CALIFORNIA, AND AN INCREASED DEPENDENCE ON IMPORTED PRODUCTS.

THAT IS WHY I HAVE JOINED WITH MY COLLEAGUES, MR. BLILEY AND MR. ROWLAND, IN INTRODUCING H.R. 1627, "THE FOOD QUALITY PROTECTION ACT OF 1993," WHICH WILL PROVIDE THE CERTAINTY NEEDED TO ENSURE A SAFE FOOD SUPPLY.

WHILE NO ONE ARGUES AGAINST SAFETY, OR THE NEED TO PROTECT OUR CHILDREN AND OUR ENVIRONMENT, THESE INTERESTS ARE NOT EXCLUSIVE OF THE BENEFITS DERIVED FROM PESTICIDE USE. THE TWO, IF ADEQUATELY BALANCED, CAN SERVE TO PROVIDE A HIGH QUALITY, LOW COST, DEPENDABLE FOOD SUPPLY WHICH DOES NOT THREATEN CONSUMER HEALTH.

OUR BILL HAS FOUR KEY PROVISIONS WHICH SERVE TO UPDATE OUR CURRENT FOOD SAFETY LAWS. FIRST AND FOREMOST, IT PROVIDES FOR A "NEGLIGIBLE RISK" STANDARD AND ALLOWS E.P.A. THE FLEXIBILITY TO DEFINE IT BASED ON CONSTANTLY IMPROVING SCIENCE. SECONDLY, IT CONTINUES TO ALLOW E.P.A. TO CONSIDER THE BENEFITS OF PESTICIDE USE WHEN WEIGHING ITS DECISIONS ON HOW BEST TO PROMOTE PUBLIC HEALTH. THIRD, IT SETS A NATIONAL STANDARD WHICH PROMOTES INTERSTATE COMMERCE, AND FOURTH, IT SPEEDS UP THE REMOVAL OF CHEMICALS FROM THE MARKET WHICH MAY PROVE UNSAFE.

I CAN NOT OVEREMPHASIZE THE IMPORTANCE OF ALLOWING E.P.A. THE DISCRETION TO DEFINE "NEGLIGIBLE RISK". WITHOUT IT, WE REPEAT THE MISTAKE WE MADE WITH THE "DELANEY CLAUSE" OF LOCKING IN TO CURRENT SCIENCE. WHILE THIS IS OUTSIDE OF YOUR JURISDICTION, FLEXIBILITY ON THE RESIDUE SIDE OF THE EQUATION IS ESSENTIAL TO PROTECTING THE REGISTRATION AND APPLICATION OF CHEMICALS WHICH PREVENT DRY ROT, WORM AND PEST INFESTATIONS, FUNGI, AND SCARRING.

WITHOUT THE BENEFITS THAT SUCH CHEMICALS PROVIDE, THE FOOD SUPPLY WOULD BE LIMITED AND COSTLY, AND CONSUMERS WOULD HAVE TO DEPEND ON IMPORTED PRODUCTS FOR THE FRUITS AND VEGETABLES WHICH THEY CURRENTLY TAKE FOR GRANTED. FOODS WHICH ARE EDIBLE, HEALTHY, AND NUTRITIOUS WOULD BE READILY AVAILABLE ONLY TO THOSE WHO CAN BEST AFFORD IT.

ONE MY GREATEST CONCERNS IS THE IMPACT THE DELANEY CLAUSE MAY HAVE ON MINOR USE PESTICIDES. OF ALL THE PESTICIDES USED, ABOUT 15% ARE APPLIED TO FRUITS AND VEGETABLES. ALREADY, SEVERAL MINOR USE PESTICIDES HAVE NOT BEEN REGISTERED UNDER THE 1988 "FIFRA" LAW BECAUSE THE COST OF DEVELOPING THE NEEDED DATA IS PROHIBITIVE. AN OVERLY STRINGENT APPROACH TO FOOD SAFETY REFORM WOULD SERVE AS A DISINCENTIVE TO REGISTRATION OF THESE CHEMICALS WHICH, WHILE LIMITED IN THEIR APPLICATION, ARE CRITICAL IN THEIR EFFECT.

IN YOUR CONSIDERATION OF BROADER "FIFRA" REFORM, I HOPE YOU WILL INCLUDE PROTECTION OF MINOR USES IN ADDITION TO OTHER LIMITED "FIFRA" REFORMS INCLUDED IN OUR BILL. MOST IMPORTANTLY, OUR BILL ELIMINATES THE FORMAL ADJUDICATORY HEARING REQUIREMENT FOR CANCELLATION OF PESTICIDE REGISTRATIONS. THIS SHOULD IMPROVE THE TIME FRAME FOR CANCELLATION OF UNSAFE PESTICIDES BY YEARS.

IN ADDITION, OUR BILL CALLS FOR E.P.A. TO REASSESS EACH TOLERANCE IN COORDINATION WITH THE REREGISTRATION OF PESTICIDES UNDER "FIFRA." THE BILL PROMOTES THE DEVELOPMENT OF INTEGRATED PEST MANAGEMENT TECHNIQUES, AND IMPROVES USDA'S DATA COLLECTION. WHILE I UNDERSTAND THAT THE COMMITTEE MAY GO FURTHER IN MODIFYING THE "FIFRA" LAW, I BELIEVE THE PROVISIONS IN H.R. 1627 ARE AN IMPORTANT BEGINNING.

AGAIN, I WANT TO COMMEND THE COMMITTEE FOR GOING FORWARD WITH THIS PACKAGE. I BELIEVE IT SENDS AN IMPORTANT MESSAGE TO CONGRESS AND THE ADMINISTRATION THAT FOOD SAFETY REFORM IS NECESSARY - NOW AND NOT LATER. MR. CHAIRMAN, I APPRECIATE YOUR CONSIDERATION OF H.R. 1627 WHICH HAS THE SUPPORT OF OVER 100 MEMBERS OF CONGRESS - MANY FROM THE AG. AND ENERGY AND COMMERCE COMMITTEES - AS THE FIRST STEP TOWARDS THIS IMPORTANT GOAL.

I APPRECIATE THIS OPPORTUNITY TO TESTIFY.

STATEMENT OF THE HONORABLE J. ROY ROWLAND

TESTIMONY

THE FOOD QUALITY PROTECTION ACT OF 1993

THANK YOU MR. CHAIRMAN. I APPRECIATE THE OPPORTUNITY TO TESTIFY BEFORE THIS SUBCOMMITTEE TODAY, ON BEHALF OF THE LEHMAN-BLILEY ROWLAND BILL, H.R. 1627, ALSO KNOWN AS THE "FOOD QUALITY PROTECTION ACT." THIS LEGISLATION WILL, AMONG OTHER THINGS, REFORM AND MODERNIZE THE PESTICIDE RISK TOLERANCE PROVISIONS OF THE FEDERAL FOOD, DRUG AND COSMETIC ACT (FFDCA).

THE U.S. FOOD SUPPLY IS THE SAFEST, MOST WHOLESOME AND ABUNDANT FOOD SUPPLY IN THE WORLD. TODAY'S FOODS ARE SAFE FROM PATHOGENS, DISEASES AND PARASITES AND ARE MORE NUTRITIOUS THAN EVER. PESTICIDES AND FERTILIZERS ARE CRUCIAL TO THE PRODUCTION OF OUR HIGH QUALITY FOOD SUPPLY.

CURRENTLY, THE FFDCA GIVES THE ENVIRONMENTAL PROTECTION AGENCY (EPA) RESPONSIBILITY FOR ESTABLISHING TOLERANCES FOR PESTICIDE RESIDUES IN RAW OR PROCESSED FOODS.

THE FFDCA HAS TWO SECTIONS - SECTIONS 408 AND 409, WHICH SET UP DIFFERENT CRITERIA FOR SETTING TOLERANCES FOR PESTICIDE RESIDUES IN RAW OR PROCESSED FOODS. SECTION 408 APPLIES TO RAW AGRICULTURAL COMMODITIES AND MANDATES A COST-BENEFIT APPROACH THAT BALANCES THE RISKS ASSOCIATED WITH THE USE OF A PESTICIDE AGAINST THE BENEFITS OF USING IT IN THE FOOD SUPPLY. SECTION 409, WHICH APPLIES ONLY TO PROCESSED FOODS, INCLUDES THE "DELANEY CLAUSE," WHICH PROHIBITS PESTICIDES THAT HAVE BEEN FOUND TO INDUCE CANCER IN HUMANS OR IN ANIMALS.

CONGRESS ENACTED THE "DELANEY CLAUSE" IN 1958. IT REQUIRED PROCESSED FOODS TO HAVE A "ZERO RISK" TOLERANCE OF PESTICIDES. WITH SCIENTIFIC ADVANCEMENT IN THE PAST 35 YEARS, WE CAN NOW TRACE PESTICIDES AT SUCH MINUTE LEVELS THAT THEY PRESENT AN ALMOST NONEXISTENT RISK OF CANCER. IN 1987, THE NATIONAL ACADEMY OF SCIENCES PUBLISHED A REPORT STATING THAT THE EPA SHOULD USE A "NEGLIGIBLE RISK" STANDARD, MEANING THAT THE RISK COULD BE ONE IN ONE MILLIONTH. THIS IS AN ARBITRARY STANDARD THAT SHOULD BE BASED ON SCIENTIFIC EVIDENCE. EPA ADOPTED THIS UPDATED STANDARD.

IN 1991, THE NATURAL RESOURCES DEFENSE COUNCIL FILED SUIT IN THE NINTH DISTRICT COURT IN CALIFORNIA, PROTESTING THE "NEGLIGIBLE RISK" STANDARD. THE COURT RULED IN FAVOR OF THE NRDC. IN RESPONSE TO THE DECISION, THE EPA PUBLISHED A LIST OF PESTICIDES WHICH COULD POTENTIALLY BE WITHDRAWN FROM THE MARKET. THE EPA IS EXPECTED TO MAKE ADJUSTMENTS IN THE COMING WEEKS, WHICH COULD MEAN MORE PESTICIDES WOULD BE ADDED TO THE LIST.

THE LOSS OF THESE PESTICIDES COULD INCREASE THE COSTS OF PRODUCTION FOR PRODUCERS AND THE COSTS OF COMMODITIES FOR CONSUMERS. THE AVAILABILITY AND QUALITY OF FOODS FOR CONSUMERS WILL DECREASE AS WELL. IN ADDITION, PEST PROBLEMS ARE CYCLICAL. ONE YEAR A PEST MAY HAVE THE POTENTIAL TO DEVASTATE AN ENTIRE CROP, THE NEXT YEAR THE PEST MAY DISAPPEAR. WITHOUT THE AVAILABILITY OF PESTICIDES, THE CROP ABUNDANCE MAY FLUCTUATE EACH YEAR.

THIS COULD BE DEVASTATING TO THE SOUTH AND THE SOUTHEAST. THE PRODUCTION OF FRUITS AND VEGETABLES WOULD BE DECREASED. PEANUT PRODUCTION COULD BE DISABLED. THE COSTS OF SOYBEAN PRODUCTION COULD

SKYROCKET. IN MY OWN STATE OF GEORGIA, THIS WOULD BE DISASTROUS.

H.R. 1627 WILL ADDRESS THIS PROBLEM. THIS BILL WILL IMPROVE AND UPDATE CURRENT LAW AND WILL GIVE THE EPA NECESSARY FLEXIBILITY TO EMPLOY REASONABLE RISK ESTIMATES. IT WILL STREAMLINE THE PESTICIDE CANCELLATION PROCESS. IT WILL PROVIDE A UNIFORM NEGLIGIBLE RISK STANDARD FOR PESTICIDE RESIDUES IN BOTH RAW AND PROCESSED FOODS, AS RECOMMENDED BY THE NATIONAL ACADEMY OF SCIENCES.

RECENTLY, THERE HAS BEEN INCREASED INTEREST IN RISK ASSESSMENT FOR PESTICIDES, PARTICULARLY BECAUSE OF THE NATIONAL ACADEMY OF SCIENCES RECENT STUDY ON CHILDREN AND PESTICIDES. THE NEWS REPORTS SURROUNDING THE RELEASE OF THE NAS'S STUDY HAVE BEEN DISCONCERTING. THE WASHINGTON POST HEADLINE WAS "PESTICIDE RISK MAY BE HIGHER IN CHILDREN." NEWSWEEK'S ARTICLE STATED, "BETTER WATCH THOSE FRESH FRUITS."

AS A FAMILY PHYSICIAN FOR 28 YEARS, I, TOO, HAVE CONCERNS ABOUT ANY STUDY WHICH RAISES QUESTIONS ABOUT THE HEALTH OF OUR CHILDREN, BUT WE MUST BE CAREFUL NOT TO JUMP TO ANY CONCLUSIONS ABOUT WHAT THE NAS STUDY HAS ACTUALLY DETERMINED.

THE NAS STUDY FOUND THAT, "THE CURRENT REGULATORY SYSTEM DOES NOT SPECIFICALLY CONSIDER INFANTS AND CHILDREN." IN ADDITION, THE STUDY FOUND THAT "RISK ASSESSMENT METHODS THAT ENHANCE THE ABILITY TO ESTIMATE THE MAGNITUDE OF THE EFFECTS MUST BE CONSIDERED." THE STUDY ESSENTIALLY FOUND THAT MORE DATA IS NEEDED AND A GOOD RISK ASSESSMENT METHODOLOGY SHOULD BE ESTABLISHED IN ORDER TO DETERMINE WHETHER CHILDREN ARE, IN FACT, AT RISK OF OVER-EXPOSURE TO PESTICIDES.

DR. PHILIP LANDRIGAN, WHO HEADED THIS STUDY, STATED THAT THE WHOLESAL
BANNING OF PESTICIDES AS A RESULT OF THE STUDY IS INAPPROPRIATE, AND
THAT WHAT IS REQUIRED IS BETTER MANAGEMENT OF PESTICIDE RISKS. THAT IS
EXACTLY THE INTENTION OF H.R. 1627, WHICH PROVIDES THE EPA WITH TOOLS
THAT IT NOW LACKS TO BETTER REGULATE THE USE OF PESTICIDES, AND THE
PRESENCE OF PESTICIDE RESIDUES IN FOODS.

WE MUST PROVIDE OUR GOVERNMENT'S SCIENTISTS AND REGULATORS THE
FLEXIBILITY TO DO THEIR JOBS. WE SHOULD NOT SUCCUMB TO THE TEMPTATION
TO PRESCRIBE IN INORDINATE DETAIL THE WAY EPA SHOULD DO ITS JOB.

THANK YOU MR. CHAIRMAN. I LOOK FORWARD TO WORKING WITH YOUR COMMITTEE
ON THIS IMPORTANT ISSUE.



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POSITION STATEMENT

Testimony of
Rebecca Doyle, Director
Illinois Department of Agriculture
on behalf of the
National Association of State Departments of Agriculture
before the
House Agriculture Subcommittee on
Department Operations and Nutrition
U.S. House of Representatives
August 2, 1993

re: H.R. 1627, the Food Quality Protection Act of 1993

Good afternoon. Thank you, Mr. Chairman, and members of the Subcommittee. I am Becky Doyle, Director of the Illinois Department of Agriculture. It is a pleasure to appear before this Subcommittee on behalf of the National Association of State Departments of Agriculture (NASDA) to discuss the matter of pesticide regulation. NASDA is nonprofit association of public officials representing the Commissioners, Secretaries and Directors of Agriculture in the fifty states and the territories of American Samoa, Guam, Puerto Rico, and the Virgin Islands. As the chief state agriculture officials, NASDA's members are keenly aware of the importance of balancing agricultural production and natural resource conservation on their state's and the nation's economy.

In most cases, under a cooperative agreement with the Environmental Protection Agency (EPA), the state departments of agriculture serve as the lead state pesticide agency in each state. Therefore, I bring you a unique perspective on pesticide regulations and the reauthorization of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA). In addition to NASDA, my testimony today represents the position of the Association of American Pesticide Control Officials (AAPCO). AAPCO consists essentially of state and federal pesticide regulatory officials; however, federal and provincial Canadian officials are members, as are officials of all North American countries, including heads of experiment stations, research workers, and other governmental officials with responsibility for examination of pesticides. NASDA and AAPCO members represent the frontline pesticide regulators who must balance human health and environmental protection with farmers' needs, and face the state and local anxiety over pesticide use and regulation.

BACKGROUND

Under FIFRA, EPA is responsible for registering pesticides using risk-benefit analysis to ensure that pesticide use will not result in unreasonable adverse effects on health or the environment. EPA registers a pesticide only if it determines that it will not cause any "unreasonable risk to humans or the environment, taking into account the economic, social, and environmental costs and benefits of the use

of [the] pesticide." Basically, registrations are licenses for specific pesticide uses that state the terms, conditions and cautions of these uses.

To register a pesticide, EPA requires the manufacturer to provide health and environmental effects data, product labeling information, a confidential statement of the chemical formula of the pesticide, and child-resistant packaging (if applicable) to EPA's Office of Pesticide Programs, Registration Division. It may take the applicant a few months to several years to gather the necessary data because of the time involved in completing the research required to obtain a registration. The Registrations Division decides to approve or deny the registration after reviewing a complete application. This process can take an average of two years if all the necessary data have been provided, but much longer if data is incomplete and additional data is needed.

Separate legislation guides the setting of tolerances for residues of pesticides registered under FIFRA. The Federal Food, Drug, and Cosmetic Act (FFDCA) requires EPA to establish tolerances — the maximum limits of pesticide residues allowed in or on raw agricultural commodities, processed foods, or animal feeds. Establishing a tolerance is a prerequisite to granting registration for food-use pesticides used in the United States.

In order to establish a tolerance, EPA must determine whether tolerance levels proposed by pesticide registrants will present a health risk to the consumer. Registrants are required to submit toxicology and residue data in their tolerance petitions (applications) to assess possible health and environmental risks, to identify the nature and amount of residue that could occur with proper pesticide use, and to present analytical methods that the Food and Drug Administration (FDA) can use to test the food for residues of the pesticides. EPA scientists (reviewers) use this data to assess the possible health risks of a pesticide's use on food and to determine whether proposed tolerance levels would protect the public health. FDA enforces the EPA tolerances for both domestic and imported produce.

PESTICIDE REGULATION PRINCIPLES & FIFRA PROVISIONS OF H.R. 1627

American consumers can be confident that the U.S. food supply is safe from unreasonable risks presented by pesticide residues. The food products available to U.S. consumers are safe, abundant and economical. NASDA and AAPCO do believe, however, that improvements in our pesticide laws are needed primarily due to advances in scientific technological capabilities.

As the national associations of the state lead pesticide regulatory agencies and officials, NASDA and AAPCO believe that H.R. 1627, the Food Quality Protection Act of 1993, will improve federal regulation of pesticide use and establish national uniform tolerances for residues in food based upon a "negligible risk" standard, as recommended by the National Academy of Sciences (NAS). Adoption of this legislation will allow the U.S. to continue to produce the safest, most economical, and most abundant food supply in the world. NASDA and AAPCO strongly support passage of H.R. 1627 and encourage the House Agriculture Committee to move quickly to favorably report the bill. While the provisions of H.R. 1627 should be not be changed, NASDA and AAPCO do recommend five specific amendments which will broaden the scope of the legislation, a necessary step to achieving a comprehensive reauthorization of FIFRA.

Cancellation Procedure

Removing harmful pesticides from the market takes significant time. The EPA may cancel a pesticide registration under FIFRA if information shows that the pesticide presents an unreasonable risk to human

health or the environment. However, the cancellation process can be unnecessarily time consuming and expensive, and has rarely reduced controversies about either a pesticide's continued use or EPA's ability to regulate pesticides responsibly. Legislation is needed to streamline the cancellation process while retaining provisions for public participation that would contribute to valid scientific assessments of pesticide products.

H.R. 1627 would eliminate the current formal adjudicatory hearing requirement for cancellation of pesticide registrations. It would provide for scientific committee peer review of the evidence supporting proposed cancellation; precancellation notice to pesticide registrants, the U.S. Department of Health and Human Services and the U.S. Department of Agriculture (USDA); advance public notice and comment on proposed cancellation actions; FIFRA Scientific Advisory Panel (SAP) review of cancellation proposals; and the right to an informal cancellation hearing.

Suspension

EPA's existing suspension authority is adequate and major changes are not needed. EPA has substantial authority to temporarily suspend a registration, pending permanent cancellation proceedings, if the pesticide poses an "imminent hazard." If EPA's cancellation authority is streamlined, changes in current suspension authority would be inappropriate. Changes in the "imminent hazard" threshold would curtail the public's ability to participate in the pesticide regulatory decisions on a timely basis, and could result in the inappropriate removal of essential pesticides from the marketplace. Changes would also likely be tested in court, creating needless confusion and potential delay.

H.R. 1627 would allow EPA to issue emergency suspension orders before a proposed cancellation order has been issued provided the Administrator proceeds expeditiously with the cancellation proceeding. This procedural change will continue to ensure that if a pesticide should be suspended, EPA can move in a expeditious fashion to do so.

Reregistration

Amendments to FIFRA are needed to ensure that pesticide registrations and supporting data are current. Pesticide registrants should periodically submit scientific data and other information sufficient for EPA to determine whether existing registrations are proper. This reregistration process should identify benchmarks for data submission and EPA review.

H.R. 1627 would require EPA to reassess each tolerance and exemption in conjunction with the reregistration of pesticides under FIFRA. The legislation, however, must not create a new or exacerbate the current "minor use" reregistration problem.

Federal Agency Coordination

Consultation and coordination within the federal government on food and pesticide regulations needs improvement. Currently, consultation among EPA, USDA and the Food and Drug Administration (FDA) primarily occurs in the form of written comments during cancellation of a pesticide's registration. Given the linkage among pesticide use, agricultural production and food safety, the three regulatory agencies involved must consult more effectively and regularly. Moreover, communication and coordination between the three federal regulatory agencies and the state regulatory agencies needs improvement.

H.R. 1627 would direct USDA to collect pesticide use data of statewide or regional significance for all major crops and crops of dietary significance and to coordinate with EPA to assure that the data is

appropriate for exposure and benefits calculations in connection with pesticide tolerance decisions. This pesticide use data collection is important, but only a beginning to the cooperation which is necessary. We strongly suggest that language be added which will require consultation between the federal agencies and the state agencies which must implement the programs and policies. An example of where communication has been inadequate between EPA and state agencies is the new Worker Protection Standards. While EPA has mandated that states enforce the new program as part of their regulatory efforts, the federal agency has failed to adequately respond to the financial needs, questions and concerns of state regulators.

PESTICIDE REGULATION PRINCIPLES & FFDCA PROVISIONS OF H.R. 1627

H.R. 1627 is the only comprehensive pesticide regulation bill pending before the 103rd Congress. The legislation not only amends FIFRA, but it also makes important and necessary changes to the FFDCA. No scientific advances can be made in pesticide regulation without changes in both statutes. We urge the Committee on Agriculture to encourage the Committee on Energy and Commerce to move quickly in considering the provisions in the bill over which it has jurisdiction. The amendments H.R. 1627 makes to the FFDCA are far superior to changes suggested by other legislation.

Delaney Clause

The Delaney Clause is a 1958 amendment to the FFDCA that prohibits any additive in *processed* food if the additive concentrates above a certain level, or is shown to induce cancer in laboratory animals. The Delaney Clause was enacted in response to a public outcry over the FDA's approval of the pesticide *Aramite* as a food additive. *Aramite* was then known to be carcinogenic. The Delaney Clause was initially part of a bill introduced by Representative James J. Delaney (D-NY) but was later incorporated into the Food Additives Amendment of 1958. It was intended to ensure that no carcinogens, no matter how small the amount, would be allowed in processed foods. Throughout its history, the Delaney Clause has been interpreted as an absolute ban on all carcinogenic food additives. Its rigid language is intended to safeguard against the tendency of some chemicals to concentrate when food is processed, giving consumers a more intense dose of the additives than in raw agricultural products.

In October 1988, the EPA interpreted the Delaney Clause to allow certain pesticide residues in processed foods where the human dietary risk is "at most negligible," or *de minimis*. (Literally, *de minimis* is Latin for "trivial.") With respect to registration of pesticides, a *de minimis* interpretation of the Delaney Clause permits pesticide residues in processed foods at levels above zero that were considered to be of negligible (or "trivial") risk. The EPA defined this risk as a probability of one additional cancer case for every one million persons over a 70-year expected lifetime. A negligible risk standard protects human health because it is based on very cautious animal testing that greatly exaggerates human risk. For example, according to EPA, the risk of developing cancer from eating the processed foods mentioned in the court case *Les v. Reilly* range from between one in 10 million to two in 100 billion. In contrast, fluoride in tap water, which in many cases is mandated, has a risk level of one in 10,000.

EPA's adoption of a *de minimis* interpretation came after the NAS recommended, in a 1987 report called *Regulating Pesticides in Food: The Delaney Paradox*, that EPA apply a uniform, negligible risk standard to gauge pesticide residues, rather than the Delaney Clause's zero-risk standard. The report said: "A negligible risk standard for carcinogens in food, applied consistently to all pesticides and all forms of food, could dramatically reduce total dietary exposure to [cancer-causing] pesticides with modest reduction of benefits."

For legal reasons, not health concerns, the Court of Appeals for the Ninth Circuit in July of 1992 rejected EPA's interpretation of the Delaney Clause. EPA had argued that the presence of pesticide residues in processed foods which pose a negligible risk are allowed under a *de minimis* interpretation of the Delaney Clause. In *Les v. Reilly*, the court ruled that such an interpretation violated the letter of the "zero-risk" Delaney Clause.

Because the recent court decision prohibits EPA from utilizing a *de minimis* interpretation of the Delaney Clause, EPA must now apply a literal interpretation of Delaney, and may have to review all of the tolerances that have been granted using a *de minimis* interpretation. If those tolerances violate a strict reading of the Delaney Clause, they may have to be revoked. EPA is, however, currently considering changing many of its policies (described in the February 5th *Federal Register* notice), principally those which relate to the need for a Section 409 tolerance.

By denying the petition for review, The U.S. Supreme Court let stand the Ninth Circuit's decision prohibiting EPA from establishing greater than zero tolerances for pesticide residues in food products, even if those residues pose a mere *de minimis* risk of cancer to consumers. As a result, the Delaney Clause can block the use of pesticides on some agricultural products which would otherwise be permitted under FIFRA's risk-benefit balancing test. The results will be that farmers and growers could lose many valuable pesticides, thereby increasing the cost and decreasing the availability and/or quality of fruits, vegetables, oils and grains to consumers.

The Ranking Minority Member Mr. Smith is aware of the problems *Les v. Reilly* caused for hop growers due to Section 18 cancellations. Let me share another Section 18 problem on apples in North Carolina created by *Les v. Reilly*. On February 9, 1993, the North Carolina Department of Agriculture requested a Section 18 emergency exemption for the use of *iprodione* on apples to control *alternaria* blotch. On March 26, 1993, EPA granted the emergency exemption stating that the Agency had determined "that the registered alternatives will not adequately control *alternaria* blotch." On May 7, 1993, EPA revoked the Section 18 exemption because of the new policy adopted due to the *Les v. Reilly* court decision. On May 11, 1993, the North Carolina Department of Agriculture resubmitted its request for a Section 18 exemption stating: "All possible alternatives were thoroughly evaluated prior to submitting the original application to the EPA. There are no alternative pesticides or control practices known to our specialists. If uncontrolled, this disease kills mature, bearing apple trees. These trees grow for 5 to 8 years after planting as young, grafted tree stock before they begin to bear fruit. If the disease continues to expand and increase in severity throughout the apple acreage, it has the potential to totally eliminate the red delicious production in North Carolina." On July 8, 1993, EPA gave final denial to the Section 18 request based, not on food safety reasons, but on the *Les v. Reilly* ruling.

The NAS, EPA and other authoritative scientific groups have recommended repealing the arbitrary zero-risk standard of Delaney because strict enforcement would lead to the loss of many valuable pesticides which are essential for growing many of our fruits and vegetables, and whose residues have been deemed safe by scientists and the government. They argue that the Delaney Clause no longer makes sense in light of modern science's ability to detect pesticide residues in food. Technological advances now enable detection of residues in minute quantities where the risk to human health is, for all practical purposes, negligible. Some measurements can now detect, for example, one part per quintillion.

Therefore, we believe the FFDCA should be amended to eliminate the outmoded "zero risk" Delaney Clause, replacing it with a nationwide "negligible risk" standard for pesticide residues in all food. A

narrative definition of "negligible risk," rather than a rigid numerical standard, is preferable in assessing risks based on ever-improving science which can measure minute pesticide residues. This new standard would ensure the consumer safe food products, and utilize modern risk assessment procedures and realistic consumer exposure to pesticides.

H.R. 1627 would replace the application of the Delaney Clause with a single negligible risk standard made applicable to tolerances for pesticide residues in raw commodities and processed food. EPA would be responsible for defining negligible risk in light of evolving science, taking into account different routes of exposure to a pesticide and sensitivities of population subgroups. EPA would be required, where reliable data is available, to calculate the dietary risk posed to food consumers by a pesticide on the basis of the percent of food actually treated with the pesticide and the actual residue levels of the pesticide that occur in food.

In June of this year, NAS released *Pesticides in the Diets of Infants and Children*. The report clearly suggests that when setting tolerances, regulators should be given the flexibility to set negligible risk levels based on evolving science, and not based on an arbitrary number codified in law at a specific point in time. In fact, Donald R. Mattison of the Graduate School of Public Health at the University of Pittsburgh, who served as vice-chair of the authoring committee, told the Senate Agriculture, Nutrition and Forestry Committee that pesticide regulatory agencies "need the flexibility to respond to evolving science." During a hearing on June 29, 1993, he encouraged the Senate committee to include flexibility in any legislation as opposed to rigid standards set forth in current law. H.R. 1627 provides such flexibility, whereas other legislation, such as H.R. 872, creates a rigid risk proposal. H.R. 1627 meets the flexibility needs by narratively establishing a negligible risk which allows the agency to make regulatory advances and science evolves. H.R. 872 sets a bright-line standard of one-in-a-million, without consideration of health benefits, and without the opportunity to improve regulations as science makes new discoveries. If Congress adopts the more rigid standard, we will be here in the future discussing the "One-in-a-Million Paradox" much like today we are debating the Delaney Paradox.

The NAS report also suggests a need to set tolerance levels with special considerations given to the exposure levels of infants and children. H.R. 1627 specifically requires regulators to give consideration to population subgroups when setting tolerance levels.

Risk-Benefit

Regulation of pesticide use and residues in food should continue to balance the risk and benefits of pesticides. Improvements are needed in identification, measurement and evaluation of both benefits and risks. Relevant pesticide benefits should include improvement of both the public health and welfare through an enhanced agricultural economy, and availability of foods that are nutritious, varied, economical and safe.

H.R. 1627 would make clear that EPA may establish a tolerance for a pesticide residue posing greater than a negligible risk if EPA determines that there are countervailing benefits. EPA would be directed to take into account health, nutritional and consumer benefits, including the impact of the loss of a pesticide on the availability of an adequate, wholesome and economical food supply. EPA would be precluded from considering any impact on pesticide manufacturers or distributors.

On many occasions, Mr. Chairman, you have suggested that even God himself did not create a risk free food supply. You are correct. Naturally occurring carcinogenic toxins pose a risk to human health, a

risk which crop protection chemicals have the ability to reduce. For example, aflatoxin is a naturally occurring poison and carcinogen which occurs in peanuts and corn. The use of fungicides controls aflatoxin, therefore reducing the risk associated with peanuts and corn.

We cannot overlook significant health benefits and other nutritional benefits which pesticides provide. The opening paragraph of the NAS report, *Pesticides in the Diets of Infants and Children*, stated: "Pesticides are used widely in agriculture in the United States. Their application has improved crop yields and has increased the quantity of fresh fruits and vegetables in the diet, thereby contributing to improvements in public health."

Uniform Tolerances

Tolerances for acceptable residues of pesticides in food should be applicable nationwide. Under current law, several states have set different tolerances that have interrupted food production and interstate distribution, and have been a source of confusion to consumers. NASDA and AAPCO believe that, with limited exceptions, tolerances established by EPA for pesticides that have been reregistered under updated FIFRA standards should have national application.

H.R. 1627 would preclude states and political subdivisions from issuing tolerance limits, warning requirements or other restrictions on pesticide residues in food different from those set by EPA for pesticides registered or reregistered by EPA after April 25, 1985. States would be permitted to petition EPA for approval of a different tolerance limit on the basis of compelling local conditions.

AMENDMENTS TO H.R. 1627

While H.R. 1627 is a sound piece of legislation whose current provisions should not be changed, there are a few areas which the Food Quality Protection Act of 1993 fails to address. To properly amend FIFRA, the following should be added to H.R. 1627.

Minor Use Pesticide Amendment

Mr. Chairman, this Subcommittee held a full day of hearings on June 10, 1993 on the problem FIFRA '88 created for the so-called "minor use" crops. I will not revisit that hearing other than to suggest the members review the testimony of my colleague New Jersey Secretary of Agriculture Arthur R. Brown, Jr.

SUGGESTED AMENDMENT

Chairman Kika de la Garza has introduced legislation, H.R. 967, which I believe, and the majority of witnesses on June 10 stated, will go along way to correcting this inadvertently created problem. NASDA and AAPCO support H.R. 967 and strongly recommend that it be included in H.R. 1627 before being reported to the full House. While the issue is an economic one, and not a food safety issue, it is extremely important to pass H.R. 967 as introduced as soon as possible.

Federal Preemption Amendment

On June 21, 1991, in the case *Wisconsin Public Intervenor, et al. v. Mortier et al.*, the United States Supreme Court held (9 to 0) that FIFRA does not preempt local government regulation of pesticide use. The case arose when the town of Casey, Wisconsin (population 404) passed a series of increasingly restrictive ordinances through the mid 1980's requiring, among other things, the issuance of a permit for application of pesticides to public lands, private lands subject to public use, or for aerial application of

any pesticide. Mr. Mortier, a Christmas tree farmer whose land was subject to the ordinance, applied for such a permit. The permit was denied. He then brought suit against the town, arguing that FIFRA preempted the town's ordinance.

A Wisconsin county court agreed. The case was appealed to the Wisconsin Supreme Court, which also held that FIFRA preempted the ordinance. The case was then appealed to the U.S. Supreme Court.

In reaching its decision, the Supreme Court reviewed various methods for finding federal preemption, including "express," "implied" and "actual conflict" preemption analysis. It received eight separate *amicus* briefs arguing points on both sides of the case, in addition to an early brief by the Justice Department urging the court to review the case. In the end, the Court concluded that although congressional committee reports arguably supported a finding of preemption, the express language of the statute itself did not provide sufficient justification for preempting local regulation of pesticides. In his written opinion, Justice Byron R. White reasoned that because FIFRA did not actually address or provide the type of detailed regulations concerning pesticide use found in the Casey, Wisconsin ordinance, it could not be said to preempt all local regulation.

However, the Court was mindful of the potential chaotic effect of its decision on the "real world" of pesticide use and regulation. Fully aware that approximately 83,000 local jurisdictions with potentially "insufficient expertise" would be free to regulate pesticide use on their own, Justice White concluded the written opinion by suggesting that Congress revisit the issue of the appropriate role of local government when he said "... Congress is free to find that local government regulation does wreak such havoc and enact legislation with the purpose of preventing it. We are satisfied, however, that Congress has not done so yet." (*Emphasis added*)

Pesticide use regulations are best enacted and coordinated at the state level or higher. In this way, conflicting and overlapping regulations may be avoided, and greater access to scientific expertise and input is available. With greater citizen input at the state level, action taken will benefit all residents of the state rather than one isolated town or village. NASDA and AAPCO support sensible, uniform federal/state regulation of pesticides through passage of preemptive legislation, while allowing local input into the federal/state regulatory process.

Public Policy Arguments of Preemption of Local Regulation — Many people mistakenly believe that "preemption of local regulation" would deprive citizens of a voice in the decision-making process, and place pesticide use regulation solely in the hands of EPA. Such is not the case. Even if local regulation is preempted by either state or federal law, states would continue to have the right to regulate in the subject area, and local citizens would continue to be able to participate in the regulatory process at the state level.

Lack of Expertise — In current practice, local regulation of pesticide use has included bans on particular products (in one case banning several products not manufactured for 20 years), advance notice of application, posting of warnings, and applicator licensing and certification programs, among others. However, local governments have traditionally not employed the scientific or technical experts necessary for effective, informed decision making in the area of pesticide regulation. The resulting regulations are therefore likely to be arbitrarily written, vary widely, and governed by no discernable, scientifically-based standard.

Those supporting local regulation argue that most local regulations now being adopted merely concern advance notice and posting requirements — areas which do not require any special training or expertise. It is true that such requirements are components of most new local regulation. However, virtually all local regulations have additional components such as training and certification requirements, product bans, or even "environmental impact" preambles which pass judgment on the alleged danger, toxicity, efficacy and desirability of certain products. These types of judgments cannot be accurately made without some specialized scientific education or training.

Conflicting/Overlapping Regulation — When pesticide use regulations are generated by several local governments throughout a state, there is a strong possibility that no two will be exactly alike. Without coordination among adjoining and overlapping jurisdictions (i.e., a city within a county), regulations will overlap and/or conflict with one another. For businesses and user groups which operate in more than one jurisdiction (including many farms and virtually all pest control, lawn care and right-of-way maintenance companies), compliance with differing regulations can become difficult, expensive or impossible.

The counter-argument most commonly presented to this point is that local governments must exercise their "police power" to protect their citizens, by responding to local environmental concerns, regardless of the activity or inactivity in neighboring jurisdictions. To the degree that an environmental need for greater regulation exists, it is unlikely that such a need is confined within the artificial borders of a local jurisdiction. Consequently, comprehensive solutions can best be accomplished through a coordinated effort — across political subdivisions — at the state level. In addition, preemption of local regulation does not equate to a lack of opportunity for local input. Therefore, the proper source of regulation and place for citizen input would not be with just one government, but rather with state regulatory officials who have greater access to experts with scientific knowledge and an understanding of the regulations of other jurisdictions.

State v. Local Interest — A primary motivator behind local pesticide use regulation is the protection of the public and environment from misuse (and in some cases, use) of pesticides. However, unlike issues such as taxes for schools, sewer and utility services, and fire and police protection, the proper regulation of pesticides is not an issue of purely local concern. Particularly in larger, urban areas, the issue of pesticide use regulation is one of, at least, regional concern. While it is true that political subdivisions cannot be deprived of the right to legislate on purely local affairs germane to the purposes for which the subdivision was created, the traditional view of a state's police power places regulation of matters of state-wide concern, such as pesticide use regulation, in the hands of the state government.

Advocates of local regulation argue that it is only through local regulation that local concerns can be addressed or solved. Simply put, this is incorrect for two reasons. First, FIFRA not only gives states primacy in the areas of applicator training and certification (by authorizing matching federal funds for such educational programs), but also gives states the authority to regulate the sale and use of pesticides. Second, state statutes could be tailored to address only a specific local area. One benefit of having citizen input at the state level is that regulations, once enacted, would benefit citizens of the *entire* state, not just an isolated locality.

The experience of working with federal and state governments would suggest to some that improvements in regulations may be needed. However, the answer to ineffective regulation is not to add another layer of regulation, but to fix existing regulations.

Cost — There is no question that any type of local regulation costs local citizens money. At a minimum, municipal staff will be needed for administration of notification registries, advance notice and posting programs, and applicator certification and licensing programs. Tests will need to be developed and administered. Compliance monitoring and enforcement efforts must be undertaken to make the regulations work and inspectors must be hired.

These additional expenses will have to be paid for in one of three ways — (1) additional taxes; (2) cuts in existing programs; or (3) assessment of user fees. Even if special user fees are assessed in an attempt to offset these costs, the additional costs to pest control companies will ultimately be passed on to consumers of pest control services, which include hospitals, restaurants and nursing homes, as well as typical homeowners.

Legal Arguments for Preemption of Local Regulation

Political Subdivisions Possess Only Such Authority as is Granted by the State — A general rule of municipal law is that political subdivisions of a state are *not* sovereign entities. Rather, they are subordinate government instrumentalities, created by the state to assist in carrying out state governmental functions. Being legislatively created, they possess only such authority as is granted to them, together with the powers reasonably incident to the authority conferred. If the "enabling" legislation which created the local unit of government does not grant a specific right or power to the local government, that right or power is reserved to the state. Consequently, unless the enabling legislation of a subdivision includes the power to regulate pesticide use, or the power to enact environmental legislation, such regulation will be *void ab initio* (void from the moment it passes).

A State May Preempt by Exercising its Police Power — The state is a sovereign unit, and the principle of preemption flows from this sovereignty. The authority to legislate on particular matters (such as pesticide regulation) is granted by the state. However, under constitutional principles (both federal and state) political subdivisions cannot be deprived of the right to legislate on purely local affairs germane to the purpose for which the subdivision was created.

For instance, a local government may impose a special tax or increase service charges for water/sewer services in order to increase revenues for a general fund. This is because water and sewer services are purely local endeavors, and the revenues generated thereby will be locally spent. Regulation of pesticide use, however, does not fall within the confines of purely local affairs germane to the creation of a subdivision and the exercise of inherent governmental functions (i.e., sewage and sanitation systems, light, water and electricity services, and police and fire protection). Instead, pesticide regulation falls under a state's general law concern; it affects statewide, public interest rather than merely local interests. As a general concern of the state acting in the character of a state, pesticide regulation prompts the exercise of a state's police power.

The Goal of Uniform Regulation Warrants Preemption — In determining whether a local regulation is preempted by a state or federal law, the first question is whether the intent to preempt is explicit or implicit in the legislation. Where the intent to preempt must be implied, the issue is not whether it is the state/federal government or the locality which has an interest in the subject matter, for usually both have the same interest. Rather, the issue is whose interest, the state/federal government or the local jurisdiction, is paramount.

A state or federal government's interest is paramount to a local jurisdiction when the state or federal government has acted on a subject, and in so acting, has evidenced a policy mandate that varying local laws be preempted. The principles of preemption are designed with a common end in view — to avoid conflicting regulation of conduct by various official bodies which might have some authority over the subject matter. By placing use regulations at the state level, the goal of uniformity is attained.

Examples of Excessive Local Regulations — A number of local regulations show the excessiveness of local regulations:

- A Mansfield, Massachusetts ordinance required notification of pesticide use by posting a pink sign, exactly 11" x 8-1/2", although a preexisting Massachusetts state law required posting of a 4" x 5" yellow sign with bold, black letters.
- An ordinance proposed in Koshkonong, Wisconsin would require posting of a warning sign (containing seven separate information statements) for 48 hours prior to, and *6 months after*, any application of pesticides. In addition, a "Special Waste Permit" would have to be issued by the Town Board prior to virtually all pesticide applications.
- A Plum, Pennsylvania ordinance required homeowners to be *at home* during any fumigation of a home.
- The preamble to a proposed ordinance in Denver, Colorado states that "wind" is a "unique" local condition which justifies restrictions on certain types of application of pesticides, including any application over five feet off of the ground.
- The Minneapolis Environmental Commission has recommended forming citizen patrols to monitor neighbors' pesticide use. The "MEC" also urges use of "reusable plastic signs" as part of a posting and notification plan, requiring that they be in place before and *during* application, even though the signs might not be free from pesticide residues after repeated exposure to multiple products from prior users.
- A proposed ordinance in Agawan, Massachusetts would make it illegal to spray pesticides between 6 pm and 8 am, meaning that most pesticide applications to schools and day care centers would have to be made when children are present.
- Fayetteville, Arkansas banned all herbicides, significantly restricting and delaying research by weed scientists at the University of Arkansas by nearly two years.
- The Stone County, Arkansas "Quorum Court" has been asked to ban all pesticide use in the county, although no health or environmental problem has been shown to exist.
- The myriad of pre-application notification and posting requirements proposed in Missoula, Montana would have applied not only *within* the city limits, but also "five miles outside city limits." The posting would have required signs with "frown faces" and the international circle with a slash through a family with a dog.

- A proposal in Lake Winnebago, Missouri banned not only products which have not been registered or available for over 20 years (2,4,5,T, DDT, endrin, dieldrin, toxaphene), but also commonly used products (simazine, lindane, 2,4,D, diazanon, glyphosate and Roundup), showing how arbitrarily decision can be made without scientific input.
- An ordinance in Burlington, Vermont requires the posting of the "International Mr. Yuk" symbol on signs to be placed at the perimeter of *all* places treated with pesticides.

SUGGESTED AMENDMENT

Representatives Harold Volkmer and Robert Smith will soon introduced a bill to provide express federal/state preemption of local pesticide regulation. That legislation should be added to H.R. 1627 during consideration of the bill.

Section 18 Amendment

New requirements have been instituted for the issuance of Section 18 Specific Exemptions, requiring aquatic residue monitoring and incident monitoring for bird and fish kills for future Section 18 exemptions of certain chemicals. This burdensome requirement seems to contradict an October 29, 1992 decision on registration and reregistration requirements made by Linda Fisher, then-Assistant Administrator for Prevention, Pesticides and Toxic Substances, based on the recommendation of the Ecological, Fate and Effects Task Force. In the October 29 memorandum, Ms. Fisher stated:

More specifically, OPP [Office of Pesticide Programs] will no longer require avian and aquatic field testing, except in unusual circumstances. Rather, decisions will be based on lab testing, incident data and other information which can easily be collected to enable the program to better characterize potential risk.

While the above policy was specifically designed for registration and reregistration, it appears to be inconsistent and unnecessary to require such field data on a Section 18 exemption when no such requirement is placed on the registration of the product. The Task Force making the recommendations was comprised of OPP's managers and analysts, and participants from the Office of Planning Policy and Evaluation, the Office of Pollution Prevention and Toxics, the Office of General Counsel, and the Office of Research Development. Use of this distinguished workgroup's recommendation on Section 18 exemptions would seem appropriate rather than impose detailed monitoring for the exempted crop when such requirements are not placed on the registered crop. Ms. Fisher said in her memorandum that "these decisions, once implemented, will result in protective and timely decisions in the area of ecological risk management." As you certainly are aware, the granting of Section 18 emergency exemptions is vital to production agriculture. NASDA and AAPCO believe that rescinding the requirement for aquatic residue and avian incident monitoring would not only make the Agency's requirements consistent, but will also assist in meeting the objectives of both ecological risk management and agricultural production.

SUGGESTED AMENDMENT

Language should be incorporated in H.R. 1627 which would prevent EPA from requiring avian and aquatic field testing, except in unusual circumstances. Rather, decisions should be based on lab testing, incident data and other information which can easily be collected to enable the program to better characterize potential risk in an emergency situation.

Pesticide Recordkeeping Amendment

Section 1491 of the Food, Agriculture, Conservation, and Trade Act of 1990 (FACT Act) requires certified applicators of federally restricted use pesticides (RUPs) to maintain records of such use. The FACT Act obligates the Secretary of Agriculture, in consultation with the Administrator of the EPA, to require all certified applicators to maintain records on RUPs. EPA, in accordance with the statutory provisions of FIFRA, also requires commercial certified applicators to maintain records of RUP applications. As a result, the FACT Act regulations overlap some of the requirements imposed by EPA on commercial certified applicators of RUPs.

In order to avoid duplication of regulatory effort and promote efficiency of the federal government, USDA and EPA intend to enter into a Memorandum of Understanding (MOU) to define their respective responsibilities concerning the recordkeeping rules. Preliminary plans are for EPA to have the responsibility over commercial applicators, while USDA has authority over private applicators since Section 11 of FIFRA explicitly prohibited EPA from requiring records from private applicators.

SUGGESTED AMENDMENT

The Subcommittee should adopt an amendment to H.R. 1627 to codify the intent of the USDA/EPA MOU.

Certification and Training Amendment

EPA has the authority to categorize a chemical as a Restricted Use Pesticides (RUPs). From time to time chemicals are placed in this category to increase control over the product's use and ensure applicators are trained in order to decrease the risk associated with the its use.

NASDA and AAPCO have some series concerns. however, with the current operation of the certification and training program. Those concerns range from the funding mechanism, to the lack of testing requirements, to the information being used in the educational program. For example, while H.R. 1627 will amend FIFRA to require EPA and USDA to research, develop and disseminate IPM techniques that would facilitate reduction of the use of pesticides that pose a greater than negligible risk, with special focus on minor crop use, under current law, EPA can not require states to teach IPM techniques.

Suggested Amendment

The Subcommittee should adopt language to enhance and improve the certification and training program. NASDA staff is currently developing exact recommendations needed to share with the Subcommittee before markup.

SUMMARY

In summary Mr. Chairman, let me restate NASDA's and AAPCO's strong support for H.R. 1627. The Food Quality Protection Act of 1993, will improve federal regulation of pesticide use and establish national uniform tolerances for residues in food based upon a "negligible risk" standard, as recommended by the National Academy of Sciences (NAS). Adoption of this legislation will allow the U.S. to continue to produce the safest, most economical, and most abundant food supply in the world.

We do believe that five amendments are necessary to make the comprehensive bill even better. The amendments are:

- Adding H.R. 967 to the legislation to correct the inadvertent economic problems placed on "minor use" crop producers.
- Adding the Volkmer/Smith federal preemption bill to provide for an express federal/state preemption of local pesticide regulation.
- Adding language to the measure which would prevent EPA from requiring avian and aquatic field testing for Section 18 emergency exemptions, except in unusual circumstances.
- Adding language to the bill codify the intent of the USDA/EPA Memorandum of Understanding on pesticide recordkeeping.
- Adding language to enhance and improve the certification and training program.

I have asked the NASDA staff to work with the Committee Members and your staff over the August District Work Period to discuss and develop these specific recommendations for consideration during markup.

Again, thank you for the opportunity to appear before you today to share our thoughts on this important matter. I will be happy to answer any questions the Subcommittee may have.

(Attachments follow:)



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August 30, 1993

The Honorable Steve Gunderson
2235 Rayburn House Office Building
Washington, DC 20515

Dear Representative Gunderson:

During the August 2nd hearing held by House Agriculture Subcommittee on Department Operations and Nutrition on H.R. 1627, the Food Quality Protection Act of 1993, you asked me to determine what portions of H.R. 872, the Pesticide Food Safety Act of 1993, would be, in my judgement, acceptable. While your charge seems to be a simple one, the task is quite complex, and the two pieces of legislation must be viewed in their entirety.

As the national association of state lead pesticide regulatory agencies, the National Association of State Departments of Agriculture (NASDA) believes that H.R. 872 will neither improve the regulation of pesticide use nor enhance the safety of the American food supply. Adoption of this legislation will reduce the availability of our current abundant, affordable and safe food supply. H.R. 872 does not provide a comprehensive reform to pesticide regulation; establishes a rigid, unreasonable zero risk standard for raw commodities and processed foods; fails to recognize the need for uniformity of national and international food safety standards; and exacerbates the "minor use" pesticide availability problem.

As I stated at the hearing, NASDA fully supports the passage of H.R. 1627. NASDA believes that H.R. 1627 will improve federal regulation of pesticide use and establish national uniform tolerances for residues in food based upon a "negligible risk" standard, as recommended by the National Academy of Sciences. Adoption of this legislation will allow the U.S. to continue to produce the safest, most economical, and most abundant food supply in the world.

It is not in the best interest of producers or consumers to try to piece together two very different pieces of legislation. That approach is why our current pesticide regulation system is inadequate and inappropriate. I would strongly encourage you to look at the debate in a comprehensive fashion — amending both FIFRA and the Federal Food, Drug, and Cosmetic Act. Only after a comprehensive review and reform of pesticide regulation will American consumers believe the government is providing adequate protection.

I have enclosed NASDA's Position Statements on both pieces of legislation. I hope they are useful to you in the continuing debate.

Sincerely,

Rebecca Doyle
Director, Illinois Department of Agriculture

cc: The Honorable Charles W. Stenholm
The Honorable Robert F. Smith

Richard W. Kirchhoff, Executive Vice President & Chief Executive Officer

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POSITION STATEMENT

H.R. 1627, FOOD QUALITY PROTECTION ACT OF 1993

NASDA POSITION

American consumers can be confident that the U.S. food supply is safe from unreasonable risks presented by pesticide residues. The food products available to U.S. consumers are safe, abundant and economical. The National Association of State Departments of Agriculture (NASDA) does believe, however, that improvements in our pesticide laws are needed primarily due to advances in scientific technological capabilities.

As the national association of the state lead pesticide regulatory agencies, NASDA believes that H.R. 1627, the Food Quality Protection Act of 1993 will improve federal regulation of pesticide use and establish national uniform tolerances for residues in food based upon a "negligible risk" standard, as recommended by the National Academy of Science. Adoption of this legislation will allow the U.S. to continue to produce the safest, most economical, and most abundant food supply in the world. NASDA strongly supports passage of H.R. 1627, introduced by Representatives Lehman (D-CA), Bileley (R-VA), and Rowland (D-GA), in the 103rd Congress. The bill has three main sections which address the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), Data Collection, and the Federal Food, Drug, and Cosmetic Act (FFDCA).

FEDERAL INSECTICIDE, FUNGICIDE AND RODENTICIDE ACT

Cancellation Procedure

The bill would eliminate the current formal adjudicatory hearing requirement for cancellation of pesticide registrations. It would provide for scientific committee peer review of the evidence supporting proposed cancellation; precancellation notice to pesticide registrants, the U.S. Department of Health and Human Services and the U.S. Department of Agriculture (USDA); advance public notice and comment on proposed cancellation actions; FIFRA Scientific Advisory Panel (SAP) review of cancellation proposals; and the right to an informal cancellation hearing.

Suspension

The bill would allow the Environmental Protection Agency (EPA) to issue emergency suspension orders before a proposed cancellation order has been issued provided the Administrator proceeds expeditiously with the cancellation proceeding.

Tolerance Reevaluation

The bill would require EPA to reassess each tolerance and exemption in conjunction with the reregistration of pesticides under FIFRA.

DATA COLLECTION

Pesticide Use Information

The bill would direct USDA to collect pesticide use data of statewide or regional significance for all major crops and crops of dietary significance and to coordinate with EPA to assure that the data is appropriate for exposure and benefits calculations in connection with pesticide tolerance decisions.

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Integrated Pest Management (IPM) Incentives

The bill would amend FIFRA to require EPA and USDA to research, develop and disseminate IPM techniques that would facilitate reduction of the use of pesticides that pose a greater than negligible risk, with special focus on minor crop use.

FEDERAL FOOD, DRUG, AND COSMETIC ACT*Negligible Risk Standard*

The bill would replace the application of the Delaney Clause with a single negligible risk standard made applicable to tolerances for pesticide residues in raw commodities and processed food. EPA would be responsible for defining negligible risk in light of evolving science, taking into account different routes of exposure to a pesticide and sensitivities of population subgroups. EPA would be required, where reliable data is available, to calculate the dietary risk posed to food consumers by a pesticide on the basis of the percent of food actually treated with the pesticide and the actual residue levels of the pesticide that occur in food.

Benefits

The bill would make clear that EPA may establish a tolerance for a pesticide residue posing greater than a negligible risk if EPA determines that there are countervailing benefits. EPA would be directed to take into account health, nutritional and consumer benefits, including the impact of the loss of a pesticide on the availability of an adequate, wholesome and economical food supply. EPA would be precluded from considering any impact on pesticide manufacturers or distributors.

Pass-Through Provision

The bill would retain the current law which provides that pesticide residues in processed food are legal, and that no separate tolerance is required, as long as the level of the pesticide in the processed food when ready to eat does not exceed the raw product tolerance.

Pipeline

The bill would provide that, where a pesticide tolerance is revoked, food legally treated with the pesticide prior to revocation could be sold in the ordinary course of trade unless shown to pose an unreasonable dietary risk.

International Harmonization

In establishing a tolerance, the bill would require EPA to take into account CODEX recommended international residue limits (MRLS) and to explain any departure from CODEX limits.

Metabolites and Degradation Products

The bill would provide that a tolerance for a pesticide chemical shall be regarded as covering metabolites and degradation products of the parent compound so long as the combined residues of the parent compound and any degradation products do not exceed the tolerance level and the tolerance does not explicitly exclude breakdown products.

National Uniformity

The bill would preclude states and political subdivisions from issuing tolerance limits, warning requirements or other restrictions on pesticide residues in food different from those set by EPA for pesticides registered or reregistered by EPA after April 25, 1985. States would be permitted to petition EPA for approval of a different tolerance limit on the basis of compelling local conditions.

Data Call-In

The bill would empower EPA to demand submission of additional data reasonably required to support continuation of a tolerance but only to the extent that the data could not otherwise be obtained under the data call-in procedures of FIFRA or a test rule under the Toxic Substance Control Act.



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POSITION STATEMENT

S. 331/H.R. 872, PESTICIDE FOOD SAFETY ACT OF 1993

NASDA POSITION

American consumers can be confident that the U.S. food supply is safe from unreasonable risks presented by pesticide residues. The food products available to U.S. consumers are safe, abundant and economical. The National Association of State Departments of Agriculture (NASDA) does believe, however, that improvements in our pesticide laws are needed primarily due to advances in scientific technological capabilities.

As the national association of state lead pesticide regulatory agencies, NASDA believes that S. 331/H.R. 872, the Food Safety Act of 1993, will neither improve the regulation of pesticide use nor enhance the safety of the American food supply. Adoption of this legislation will reduce the availability of our current abundant, affordable and safe food supply. S. 331/H.R. 872 does not provide a comprehensive reform to pesticide regulation; establishes a rigid, unreasonable zero risk standard for raw commodities and processed foods; fails to recognize the need for uniformity of national and international food safety standards; and exacerbates the "minor use" pesticide availability problem. NASDA strongly opposes passage of S. 331/H.R. 872, introduced by Senator Kennedy (D-MA) and Representative Waxman (D-CA).

As an alternative, NASDA believes that H.R. 1627, the Food Quality Protection Act of 1993, will improve federal regulation of pesticide use and establish national uniform tolerances for residues in food based upon a "negligible risk" standard, as recommended by the National Academy of Sciences (NAS). Adoption of this legislation will allow the U.S. to continue to produce the safest, most economical, and most abundant food supply in the world. NASDA strongly supports passage of H.R. 1627, introduced by Representatives Lehman (D-CA), Bliley (R-VA), and Rowland (D-GA).

FEDERAL INSECTICIDE, FUNGICIDE AND RODENTICIDE ACT PROVISIONS

S. 331/H.R. 872 takes a narrow approach to pesticide regulation reform by amending only the Federal Food, Drug, and Cosmetic Act (FFDCA) and ignoring the critical relationship with the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA). In contrast, H.R. 1627 not only enhances the FFDCA, it also amends FIFRA by speeding the cancellation process by implementing an informal rulemaking procedure instead of the current formal adjudicatory hearing requirement; decoupling suspension procedures from cancellation; instructing USDA to collect pesticide use information; and instructing USDA to research, develop and disseminate integrated pest management (IPM) techniques. S. 331/H.R. 872 fail to address these crucial areas.

FEDERAL FOOD, DRUG, AND COSMETIC ACT PROVISIONS

Risk Standard

While S. 331/H.R. 872 would replace the application of the Delaney Clause with a single risk standard made applicable to tolerances for pesticide residues in raw commodities and processed foods, the legislation creates an unreasonable "bright line" standard using ultra conservative risk assessment models. Such models will result in a near zero risk standard.

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In June of 1993, NAS released *Pesticides in the Diets of Infants and Children*. The report clearly suggests that when setting tolerances, regulators should be given the flexibility to set negligible risk levels based on evolving science, and not based on an arbitrary number codified in law at a specific point in time. In fact, Donald R. Mattison of the Graduate School of Public Health at the University of Pittsburgh, who served as vice-chair of the authoring committee, told the Senate Agriculture, Nutrition and Forestry Committee that pesticide regulatory agencies "need the flexibility to respond to evolving science." During a hearing on June 29, 1993, he encouraged the Senate committee to include flexibility in any legislation as opposed to rigid standards set forth in current law. H.R. 1627 provides such flexibility, whereas S. 331/H.R. 872 creates another rigid risk standard. H.R. 1627 makes EPA responsible for defining negligible risk in light of evolving science, taking into account different routes of exposure to a pesticide and sensitivities of population subgroups, such as infants and children. Under H.R. 1627, EPA would be required, where reliable data are available, to calculate the dietary risk posed to food consumers by a pesticide on the basis of the percent of food actually treated with the pesticide and the actual residue levels of the pesticide that occur in food. S. 331/H.R. 872 sets an arbitrary "bright line" standard of one-in-a-million, without consideration of health benefits, and without the opportunity to improve regulations as science makes new discoveries. If Congress adopts the more rigid standard, a "One-in-a-Million Paradox" similar to the Delaney Paradox will be created.

Benefit Consideration

S. 331/H.R. 872 would entirely eliminate consideration of pesticide benefits in establishing tolerances or exemptions. H.R. 1627 preserves EPA's power to consider health, environmental, and consumer benefits in tolerance decisions on raw commodities, and extends that power to decisions for all residues on processed foods. H.R. 1627 provides no consideration for economic benefits to the registrant of manufacturer.

Congress cannot overlook significant health benefits and other nutritional benefits provided by pesticides. The opening paragraph of the NAS report stated: "Pesticides are used widely in agriculture in the United States. Their application has improved crop yields and has increased the quantity of fresh fruits and vegetables in the diet, thereby contributing to improvements in public health." Even God did not create a risk free food supply. Naturally occurring carcinogenic toxins pose a risk to human health, a risk which crop protection chemicals have the ability to reduce. For example, aflatoxin is a naturally occurring poison and carcinogen which occurs in peanuts and corn. The use of fungicides controls aflatoxin, therefore reducing the risk associated with peanuts and corn.

Uniform Standards

S. 331/H.R. 872 fails to address the need for international harmonization and national uniformity of food safety laws. On the other hand, H.R. 1627 provides for national uniformity of tolerances for pesticides registered or reregistered under the safety data required by EPA in 1985. To avoid interruption of food production and interstate distribution, tolerances for acceptable residues of pesticides in food must be applicable nationwide. H.R. 1627 also would require EPA to determine whether a CODEX maximum residue level (MRL) has been established, and if so, whether the MRL should be adopted as the U.S. tolerance. In an global economy, a thorough reevaluation of food safety laws must include internal harmonization.

Minor Use Problem

In 1988, FIFRA was amended to accelerate the reregistration process, imposing strict and unrealistic time schedules for completion of all registrations and instituting fees for maintaining registration of products and reregistering active ingredients. The registration or reregistration of a pesticide with the EPA can involve more than 200 scientific data requirements. Because sales from "minor use" pesticides do not pay for the high cost of generating the data required by EPA, pesticide manufacturers are — for economic reasons — voluntarily dropping smaller volume minor use products scheduled for registration under the compressed schedule of FIFRA 88; and deferring registering new products or uses for "minor crops."

Data call-ins and reevaluation provision on S. 331/H.R. 872 will place further burdensome requirements on "minor use" registrants without enhancing food safety, and in some cases the loss of "minor use" pesticides is detrimental to consumer health. While H.R. 1627 does not solve the "minor use" problem, it does not make the problem worse. To solve the "minor use" problem, Congress should pass S. 985/H.R. 967, the Minor Crop Pesticide Act of 1993.

Prepared Testimony of
Sherwin Gardner
Senior Vice President for Science and Technology
Grocery Manufacturers of America, Inc.

Mr. Chairman and Members of the Subcommittee on Department Operations and Nutrition, I am Sherwin Gardner, Senior Vice President for Science and Technology of the Grocery Manufacturers of America, Inc. (GMA). GMA is an 85-year old national trade association comprised of over 130 companies which manufacture food and other products sold in retail stores throughout the United States. Member companies employ over 2.5 million people nationwide and have annual sales in excess of \$280 billion that represent more than 85 percent of the packaged food sold at retail in the United States.

Mr. Chairman, GMA recognizes and greatly appreciates your long and constructive efforts in seeking to bring about reform of this nation's pesticide laws. GMA has reviewed with great interest the provisions of H.R. 1627, the Food Quality Protection Act of 1993, and we applaud the work undertaken by the bill's sponsors, Congressmen Lehman, Bliley, and Rowland, as well as the dozens of co-sponsors of the proposed legislation. This bill represents a marked improvement over a number proposals for the regulation of food-use pesticides introduced in Congress during the last decade. GMA supports passage of this legislation.

The Miller Pesticide Amendments of 1954, which added section 408 to the Federal Food, Drug, and Cosmetic Act, constituted a landmark in the history of food regulation in this country. These amendments represented the first requirements for premarket approval of substances found in the food supply, and, for nearly forty years, they have provided strong assurances to the American public that pesticide residues in or on food do not represent a significant risk to health. In 1958, however, the Delaney Clause was added to section 409 of the Act, establishing a zero-risk standard applicable to processed foods.

Changes in science and technology since the 1950s make it entirely appropriate to review and revise the Act to ensure continuation of a high standard of safety, and also to make the process of establishing residue tolerances more efficient and effective. Many of the advances in analytical chemistry and the science of quantitative risk assessment could not have been foreseen several decades ago.

Furthermore, last year's decision of the United States Court of Appeals for the Ninth Circuit in Les v. Reilly, invalidating the Environmental Protection Agency's policy of disregarding *de minimis* risks under the Delaney Clause, has complicated EPA's task of applying the statute in a rational and

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scientifically-defensible fashion. GMA believes that the agency has ample authority under the existing statute to respond to the Les decision in a reasoned manner and set tolerances to permit continued use of valuable pesticides that pose negligible risks. Nonetheless, legislative reforms would ensure that such cramped judicial interpretations of the law do not unnecessarily restrict EPA's regulatory options now or in the future.

The bill before you would make a much needed change in the Act by establishing a negligible risk standard for pesticide residues in both processed and unprocessed foods. The National Academy of Sciences recommended such a change in a 1987 report on the subject. Because these and the other proposed revisions of current law would appropriately modernize regulation of food-use pesticides, GMA endorses H.R. 1627. We would like to add the following comments on specific elements of the bill.

DISCUSSION

Negligible Risk Standard

As I just mentioned, the proposal would adopt a negligible risk standard as the basis for establishing safe pesticide residue levels in food, a modification of current law recommended by NAS. The bill specifically addresses the concerns expressed in the recent NAS report on children's exposure to pesticide residues by mandating that EPA consider these and other sensitive population groups.

The sponsors of the bill have correctly recognized that the same safety standard should apply in setting tolerances for both raw commodities and processed foods. Moreover, the standard is formulated in such a way as to allow for the consideration of new scientific knowledge and innovations in production techniques, unlike other proposals that had sought to replace the Delaney Clause with equally rigid and unscientific criteria for evaluating safety.

Equally important, the current bill retains the longstanding practice of considering the health, nutrition, and other consumer benefits--including the impact of the loss of a pesticide on the availability of an adequate, wholesome and economical food supply--when determining whether a tolerance should be permitted for a pesticide in food products. Pesticides are highly important to the production of food in this country. These chemicals indirectly promote public health by controlling disease and damage to food, and thereby providing

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nutritious and low-cost products for American consumers. The NAS recognized that the benefits of pesticide uses are an important consideration in tolerance decisions. Under the negligible risk standard set forth in the bill, EPA will be able to focus its resources on those pesticides that pose the highest overall risks to consumers.

Tolerances for Processed Foods

GMA agrees that both processed and unprocessed foods should be subject to the same negligible risk standard. Separate tolerances for raw and processed commodities are not necessary. Section 402(a)(2) of the existing statute (sometimes referred to as the "flow through provision") provides that raw commodity residues appearing in processed foods are lawful so long as these residues have been removed to the extent possible with good manufacturing practices and the concentration of such residues in the ready to eat form of the food does not exceed the raw product tolerance. The flow through provision recognizes that pesticide residues normally decrease during processing, and H.R. 1627 properly retains this provision.

Measurements of Dietary Exposure

Actual residue levels in raw agricultural commodities and processed foods are substantially below the tolerances that have been established for raw products under section 408 of the Act. This occurs because EPA exposure calculations are based on unduly conservative assumptions about pesticide use and the extent to which processing reduces any remaining residues. Application of pesticides to food crops is performed to minimize residues at time of harvest, and post-harvest processing generally reduces those residues even further. Under the bill, the agency would calculate dietary exposure levels on the basis of actual data whenever possible.

Food Products in the Pipeline

In the event that a tolerance is revoked, foods from crops lawfully treated with the affected food-use pesticide should not unnecessarily be subject to seizure and destruction. Unless EPA determines that consumption of a legally treated food would pose an unacceptable risk during the depletion of existing stocks, there is no justification for the serious marketplace disruptions and economic losses that would arise from a decision to revoke an existing tolerance and apply that decision against products "in the pipeline." The bill correctly exempts such food products.

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National Uniformity

GMA applauds the provision of the bill precluding states from issuing different tolerances, warning label requirements, or other limitations on residues in food products of pesticides registered or reregistered after April 25, 1985. Once a federal pesticide residue tolerance is established, that determination should apply uniformly. Otherwise, differing state standards, whether they are imposed directly through tolerances or indirectly through labeling requirements, will significantly burden interstate commerce. In the unlikely event that special local conditions necessitate variances from the uniform federal standard, states could petition EPA.

Streamlined FIFRA Cancellation Procedures

GMA supports the procedural revisions of FIFRA which allow expedited suspension and cancellation of pesticides when warranted, as well as the requirement that existing residue tolerances be reviewed in conjunction with the review of pesticide registrations under FIFRA. Eliminating dangerous agricultural chemicals in an expedited fashion would serve to better safeguard public health and maintain continued consumer confidence in the safety of the food supply.

CONCLUSION

In sum, Mr. Chairman, GMA supports H.R. 1627. This bill represents a balanced response to recent difficulties encountered in EPA tolerance-setting activities. Under the proposed legislation, regulatory decisions will better reflect contemporary scientific information about the risks and benefits of pesticide use in food production.

Thank you for inviting GMA to participate.

NATIONAL FOOD PROCESSORS ASSOCIATION

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Statement of

Ms. Juanita Duggan

Senior Vice President, Government Affairs

NATIONAL FOOD PROCESSORS ASSOCIATION

before the

**House Agriculture Subcommittee on Department
Operations and Nutrition**

on

H.R. 1627

"The Food Quality Protection Act of 1993"

August 2, 1993

MR. CHAIRMAN AND MEMBERS OF THE SUBCOMMITTEE, I am Juanita Duggan, Senior Vice President for Government Affairs of the National Food Processors Association (NFPA). I am accompanied by our legal counsel, Clausen Ely. We appreciate the opportunity to appear today and to address the important topics of pesticide regulation and food safety. We commend the Chairman's leadership in holding a hearing on H.R. 1627, "The Food Quality Protection Act of 1993", and in providing a forum for discussion of the critical pesticide policy choices facing EPA.

NFPA is a national trade association representing over 500 companies, including food processors, and food packaging and equipment manufacturers. NFPA maintains three research laboratories, employing over 100 scientific personnel. NFPA laboratories are widely recognized as leaders in pesticide residue testing, and NFPA maintains an extensive pesticide residue data bank. NFPA has led the food industry in developing programs to assure that processed foods do not contain illegal or excessive pesticide residues, in advocating collection and use of actual pesticide residue data in risk assessments and tolerance decisions, and in supporting Integrated Pest Management (IPM) and other techniques to minimize pesticide use.

NFPA strongly supports H.R. 1627 as a balanced and comprehensive approach to regulation of food use pesticides. H.R. 1627 would make important improvements in both the federal Insecticide, Fungicide and Rodenticide Act (FIFRA) and the federal Food, Drug and Cosmetic Act (FD&C Act). It would streamline the pesticide cancellation and suspension process, establish a consistent negligible risk standard for pesticide tolerances for raw and processed food (as recommended in the 1987 National Academy of Sciences (NAS) Report), assure appropriate consideration

of pesticide benefits and provide for national uniformity for tolerances meeting current safety standards. A fundamental underlying theme of the bill is to require EPA to collect and use the best available toxicological data, and pesticide use and residue information, in making tolerance determinations.

The strength of H.R. 1627 is reflected by the fact that it is endorsed by a broad coalition of food industry organizations, including growers, processors and retailers, and has attracted the support of 112 members of the House. This bill provides a solid foundation from which to enact long needed food safety legislation.

As the Subcommittee is well aware, on June 29, 1993, the National Academy of Sciences (NAS) published a widely publicized report on Pesticides in the Diets of Infants and Children. The NAS Report recommends collection of additional data on food consumption patterns of infants and children, improved surveillance of pesticide residues, development of toxicity testing procedures to evaluate the vulnerability of infants and children, and use of improved methods of risk assessment to take account of the unique features of infants and children.

NFPA applauds the NAS for its careful study, and we agree that better data are needed for pesticide regulatory decisions and that special emphasis should be placed on the evaluation of potential risks to infants and children. H.R. 1627 would promote both of these goals. H.R. 1627 would require EPA to obtain and use actual pesticide use and residue data rather than assuming that residues are present at maximum levels, or that processing increases the concentration of residues in finished

foods. H.R. 1627 would also direct EPA to take into account all relevant factors, including the dietary exposure levels of major identifiable subgroups of food consumers, such as infants and children, in making negligible risk determinations. EPA would have full authority to implement the NAS recommendations, and to give special attention to potential hazards to infants and children, under the broad negligible risk standard contained in H.R. 1627. To the extent that Congress perceives the need or desirability of providing further specific direction to EPA to implement the NAS recommendations, NFPA also would support appropriate amendments to H.R. 1627 to achieve that goal.

It is also important to note that reform of the Delaney Clause, as proposed by H.R. 1627, would improve EPA's ability to regulate pesticide risks, including risks to infants and children, and other population subgroups. A pesticide may present varying degrees of risk for a number of endpoints including neurological development, reproductive toxicity, the immune system, the endocrine system, as well as a risk of cancer. The Delaney Clause, as applied by EPA, has precluded the approval of many pesticides which may provide substantial risk advantages over noncarcinogenic pesticides now on the market. EPA should have sufficient flexibility to balance the competing risks and benefits that accompany the use of pesticides and to promote the use of safer pesticides for infants and children, as well as the population as a whole.

Mr. Chairman, NFPA urges Congress and the Administration to encourage the development and introduction of a wide range of pest control techniques.

Such techniques may include the use of conventional chemical pesticides, biopesticides, biologicals, or alternative production systems relying upon fewer chemical inputs. Many farmers are experiencing difficulties due to the loss of minor use pesticides. Also, farmers are frequently confronted by a marketplace that is intolerant of certain pesticides due to perceived risks or fears of controversy. For these farmers alternatives are necessary.

NFPA believes that statutory changes, such as those contained in H.R. 1627, are the best long-term mechanism for rationalizing and improving pesticide tolerance regulation. It is important to bear in mind, however, that EPA has sufficient authority under current law to avoid unwarranted revocation of pesticide tolerances, and contrary to EPA's protestations, there is no need to consider food safety legislation in a crisis atmosphere.

As has been widely reported, the U.S. Court of Appeals for the Ninth Circuit, in the case of Les v. Reilly, overturned EPA's de minimis policy and ruled that the Delaney Clause of section 409 of the FD&C Act mandates a zero risk standard for animal carcinogens in food. EPA has argued that the Ninth Circuit decision may force the Agency to revoke tolerances for a large number of valuable pesticides, with serious adverse consequences for agriculture and the food industry. This potential crisis is self-imposed, however. EPA has full authority to regulate pesticide tolerances in a manner that would minimize the impact of the Delaney Clause. In fact, there is strong evidence that that is what Congress intended.

The potential devastating loss of agricultural pesticides that we face today is not a result of the Les v. Reilly decision but of EPA's so-called coordination policy. The coordination policy is an EPA invention that should be repudiated.

EPA's coordination policy requires issuance of a section 409 food additive tolerance whenever there is a possibility that a pesticide residue might concentrate in a processed food and mandates that, if a section 409 tolerance cannot be issued (because of the Delaney Clause or otherwise), EPA must also revoke the section 408 raw product tolerance and cancel the underlying pesticide registration for the pesticide.

In September 1992, NFPA, the United Fresh Fruit and Vegetable Association, and other food groups filed a petition urging EPA to rescind its coordination policy and no longer to require separate 409 tolerances for pesticides in processed food. The NFPA petition urges EPA to follow the language and intent of the "flow-through" provision of the FD&C Act, which provides that a pesticide residue in processed food when ready to eat is lawful as long as the residue is not greater than the tolerance for the raw commodity from which the processed food is made. The NFPA petition contends that the coordination policy was never envisioned by Congress, and is based upon assumptions that have no demonstrated relation to the actual facts. Extensive data submitted in support of the NFPA petition show that actual residue levels in agricultural commodities and in processed food are well below raw product tolerances. The petition demonstrates that continuation of current EPA policy will require numerous costly tolerance revocation proceedings, will force the agency to

prohibit the use of beneficial pesticides that pose trivial risks and will thereby reduce the availability and increase the cost to consumers of nutritious fruit, vegetable, and grain products, at the very time that FDA and the medical community are recommending greater consumption of these foods to prevent disease.

In 1987, the authors of the NAS "Delaney Paradox" Report pointed out that rigid application of the Delaney Clause, together with the EPA coordination policy, would have adverse health consequences by forcing the loss of negligible risk pesticides and promoting increased use of non-carcinogenic pesticides that may pose greater risks.

There is no sound legal or public policy basis for EPA to continue its coordination policy, and EPA should not be permitted to use the policy to create an artificial pesticide crisis.

Before addressing the specific provisions of H.R. 1627, I would like to stress three important underlying points. First, NFPA strongly supports programs to develop economical and effective alternatives to pesticides, including biological, cultural and mechanical controls. We support Title II of H.R. 1627, which would direct EPA and USDA to research, develop and disseminate IPM techniques and other methods to reduce pesticide use.

Second, it is essential to recognize that pesticides provide vital benefits for American agriculture and consumers. Pesticides enhance food quality, protect against plant diseases and promote consumer welfare by assuring an adequate, wholesome and economical food supply. For these reasons, we strongly support the

provisions of H.R. 1627 that would retain consideration of benefits in pesticide tolerance decisions.

Finally, any pesticide legislation must be judged in light of its impact on minor uses. The growing loss of minor use pesticides for fruit and vegetable production poses a serious problem for the food industry and consumers. Minor uses are not economically attractive to the pesticide industry, and there is little incentive for pesticide producers to underwrite the high cost of reregistering minor uses under the data and fee requirements of the 1988 FIFRA Amendments. A growing number of pesticide producers are abandoning minor use registrations, without any consideration of the relative safety or benefits of those uses. H.R. 1627 would permit EPA to minimize loss of valuable minor use pesticides by establishing a scientifically defensible negligible risk standard, by requiring EPA to base its risk assessments on actual pesticide use and residue data, and by providing for appropriate consideration of pesticide benefits.

With this background, I would like to describe briefly the important provisions of H.R. 1627 that we support.

FIFRA AMENDMENTS

H.R. 1627 would amend both the cancellation and suspension provisions of FIFRA to enable EPA to remove hazardous pesticides from the market without unreasonable delay.

(1) **Cancellation procedure.** The bill would streamline the lengthy and cumbersome pesticide cancellation process under section 6 of FIFRA by eliminating the

current adjudicatory hearing requirement and substituting a notice and comment rulemaking procedure. This will better enable EPA promptly to cancel pesticides that pose an unreasonable risk and will assist in promoting consumer confidence in the food supply. The bill would assure an adequate scientific basis for cancellation decisions by providing for precancellation notice to pesticide registrants, HHS and USDA, advance notice and comment on proposed cancellation actions and FIFRA Scientific Advisory Panel (SAP) review of cancellation proposals.

(2) Suspension procedure. H.R. 1627 would amend section 6 of FIFRA to authorize EPA to issue an emergency suspension order before issuing a proposed cancellation notice. This would permit EPA to take prompt action against truly hazardous pesticides without the delay inherent in developing the full risk/benefit evaluation required for a cancellation notice. This provision, coupled with the 1988 FIFRA amendment which eliminated EPA's obligation to indemnify owners of existing stocks of suspended pesticides, would provide EPA with sufficient power and flexibility to suspend the registrations for pesticides that pose a true imminent hazard.

FD&C ACT AMENDMENTS

H.R. 1627 offers a comprehensive and balanced approach to pesticide tolerance regulation. It would improve current law by providing for a uniform negligible risk standard for pesticide residues on raw and processed food, by requiring use of

actual data, rather than unrealistic assumptions, in risk assessments and by assuring national uniformity of tolerances that meet current EPA safety requirements.

(1) Negligible Risk Standard. H.R. 1627 would provide that a pesticide tolerance shall be deemed to protect the public health if the dietary risk to consumers from exposure to the pesticide is negligible. This would implement the 1987 NAS recommendation for a uniform negligible risk standard for pesticide residues in food, would give EPA flexibility to ignore insignificant risks and would permit the Agency to focus its limited resources on the highest risk pesticides. Because science and the degree of knowledge and confidence in cancer risk assessment is constantly evolving and improving, the definition of negligible risk would not include a specific risk level. Instead, EPA would be directed to take into account all relevant data in making negligible risk determinations. NFPA opposes codification of a numerical negligible risk level, or prescription of rigid risk assessment assumptions, because EPA needs the flexibility to keep pace with scientific developments. Specific statutory prescriptions of this kind recreate the undesirable rigidity of the Delaney Clause, foster litigation and prevent EPA from focusing its limited resources on the most hazardous pesticides.

(2) Dietary Exposure Calculations. Under H.R. 1627, EPA would be required, to the extent possible, to calculate dietary exposure on the basis of the percent of raw agricultural commodities or processed food actually treated with a pesticide, and on the basis of the actual residue levels detected in treated commodities and the processed food produced from those commodities. This would help avoid exaggerated

and unjustified exposure calculations and would assist in developing more realistic risk assessments. In the past, EPA has often assumed that residues occur in 100 percent of commodities for which treatment is legal and at full tolerance levels. Food industry and FDA studies have shown that these assumptions, which greatly inflate risk estimates, are unwarranted.

(3) Consideration of Pesticide Benefits. H.R. 1627 would make clear that EPA retains authority to establish a tolerance for a pesticide residue posing greater than a negligible risk if EPA determines that there are countervailing benefits. EPA would be directed to take into account health, nutritional and consumer benefits, including the impact of the loss of a pesticide on the availability of an adequate, wholesome and economical food supply. No consideration would be given to impacts on pesticide producers or distributors. Appropriate consideration of pesticide benefits in tolerance decisions, as provided for in H.R. 1627, provides recognition of the valuable role of pesticides in American agriculture and is consistent with the risk/benefit standard for pesticide registrations under FIFRA.

(4) Flow-through provision. H.R. 1627 would retain the flow-through provision of current law. Under the flowthrough provision, where a tolerance or exemption is in effect for a pesticide chemical on a raw agricultural commodity, a residue of that chemical in a processed food made from the raw agricultural commodity is considered safe as long as the level of the residue in the processed food when ready to eat is not greater than the tolerance prescribed for the raw commodity. This avoids

the necessity of establishing separate tolerances for pesticide residues in processed food and provides recognition of the fact that, in the vast majority of cases, pesticide residues are greatly reduced and do not concentrate in processed food.

(5) Metabolites and Degradation Products. H.R. 1627 would codify EPA's existing policy with respect to pesticide metabolites and degradation products in food. Under that policy, quantities of a metabolite or degradation product in a food are considered to be subject to the established tolerance for the precursor chemical, unless EPA has determined that the metabolite or degradation product is likely to pose a different or greater health risk, the combined level of the metabolite or degradation product and the precursor chemical is above the tolerance for the precursor chemical, or the tolerance specifically excludes the metabolite or degradation product. This policy avoids the increased registration costs, administrative burdens and enforcement complexities of establishing multiple separate tolerances for metabolites and degradation products where there is no valid public health reason for doing so.

(6) National Uniformity. A cornerstone of NFPA's legislative program is support for a strong national uniformity provision for pesticide tolerances that meet current data requirements. H.R. 1627 contains a sound uniformity provision that is consistent with NFPA's goals.

Under current law, states may set tolerances for pesticide residues in food that are lower than those established by EPA, and may impose warning requirements for food containing pesticide residues determined to be safe by EPA. In recent years,

a number of states have set lower tolerances than EPA for certain pesticides, creating significant burdens on interstate commerce. In addition, California Proposition 65, and similar laws under consideration in other states, may impose warning requirements on food containing pesticide residues that EPA has determined to be safe. For these reasons, it is important to mandate national uniformity of tolerances for pesticides meeting current safety data requirements. This would secure EPA leadership in pesticide tolerance decision-making and avoid the consumer confusion and substantial burdens on interstate commerce caused by special state tolerance requirements. The uniformity provision of H.R. 1627 would achieve these goals. At the same time, consumer protection would be assured by limiting required uniformity to pesticide tolerances supported by full scientific testing, and states would be permitted to petition EPA to set a lower tolerance if warranted by special local circumstances.

(7) Pipeline Provision. H.R. 1627 would provide that, where a tolerance or exemption for a pesticide chemical has been revoked, suspended or modified, a food that was legally treated with the pesticide shall not be deemed unsafe as long as the pesticide residue does not exceed the previously authorized tolerance level. EPA would retain the power to declare legally treated food unlawful, but only on the basis of a determination that consumption of the legally treated food during the period of its likely availability in commerce would pose an unreasonable dietary risk. This provision would protect against unnecessary destruction of legally treated food, would prevent massive economic loss and marketplace disruption, and would assure that food producers are

not unfairly penalized for use of legal pesticides that are subject to unpredictable regulatory action at a subsequent date.

(8) International Harmonization. With increasing international trade in food products, and U.S. government efforts to reduce trade barriers, it is important that meaningful steps be taken to promote international harmonization of pesticide tolerances. Consistent with this goal, H.R. 1627 includes a provision requiring EPA to take into account, and justify any departure from, recommended international pesticide maximum residue levels issued by Codex.

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We commend the Subcommittee for opening a dialogue on H.R. 1627, and we stand ready to work with the Congress to develop food safety legislation that will give EPA the tools necessary to reach reasonable and scientifically defensible tolerance decisions.

STATEMENT OF THE AMERICAN FARM BUREAU FEDERATION
TO THE HOUSE AGRICULTURE SUBCOMMITTEE ON
DEPARTMENT OPERATIONS AND NUTRITION REGARDING H.R. 1627,
"THE FOOD QUALITY PROTECTION ACT OF 1993"

Presented by Harry S. Bell
Vice President
American Farm Bureau Federation
and
President of the
South Carolina Farm Bureau

August 2, 1993

Hello, my name is Harry Bell. The American Farm Bureau Federation appreciates the opportunity to address the important issues raised by H.R. 1627, the "Food Quality Protection Act of 1993."

I would first like to express the frustration of farmers everywhere over the current controversy and concern about pesticides and food safety. Such concern would be more understandable if farmers were not already reducing pesticide use. National Agricultural Statistics Service surveys indicate that farmers are changing the way they farm. We are switching to new techniques such as integrated pest management (IPM) and biological controls. Further reductions in pesticide use will only come if research on alternatives is readily available to farmers. If you tell cotton growers how to control whiteflies without insecticides, they will do it. If you tell potato growers how to control late blight without fungicides, they will do it. If you tell apple growers how they can control apple scab without fungicides, they will do it. Farmers have proven time and time again that when effective, economically sound new technologies become available they will adopt them and adopt them quickly.

Farmers believe that the food they produce is safe. You will no doubt hear during these proceedings that our food supply is not safe. You will hear that dangerous pesticide residues are common in our food supply. And you will hear that unless we make pesticide rules and regulations more rigid, this danger will continue.

The public's perceived concern over food safety is shared by farmers. But our

on the belief that simply canceling pesticides improves food safety ignores the real-

world damage that pests inflict upon crops and ignores the changes in farming practices and integrated approaches that farmers are already using to reduce pesticide use.

While criticism may be directed at our nation's pesticide regulatory system, there can be no mistake that wholesale cancellation of registered pesticides will ultimately hurt farmers. Our perspective on these issues is clear. We agree with former U.S. Surgeon General Dr. C. Everett Koop's statement, "I do not know of a single instance where exposure to pesticides on foods in the marketplace is a source of any danger to children or adults. It's a risk of zero."

Farm Bureau supports H.R. 1627 because it takes a comprehensive, common sense and balanced approach to pesticide regulation. Specifically, we support the bill because it replaces the outdated Delaney Clause with a single negligible risk standard for pesticide residues in processed foods. Strict enforcement of the Delaney Clause is the worst of all possible worlds because it means simply this: higher food prices with no gain in food safety. Under a strict enforcement of Delaney, the widespread pesticide cancellations required would do nothing to improve food safety. In fact, for some crops and pests, the enforcement of the current Delaney standard may lead to increased use of other pesticides. There is every compelling reason to change the 35-year-old Delaney Clause.

Already, farmers have felt the pinch from enforcement of a zero risk standard. Apple growers in North Carolina lost a Section 18 emergency exemption (Rovral) for control of alternaria due to strict application of the Delaney Clause. I invite you to go to North Carolina so you can see the impact from the loss of one critical compound. Then try to explain to these apple growers how alternaria damage improves food safety.

We also support provisions in H.R. 1627 that resolve the differences between the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) and the Federal Food, Drug and Cosmetic Act (FFDCA) as they relate to pesticide registration and the tolerance setting process. These provisions would align pesticide regulation with recommendations made in the 1987 National Academy of Sciences (NAS) report, "Regulating Pesticides in Food: The Delaney Paradox." The "Delaney Paradox," as described in the NAS report, stems from the contradictory regulation in the risk/no benefit Delaney Clause vs. the risk/benefit standard in FIFRA. The "paradox" in the law is that strict compliance to the Delaney Clause prevents newer, safer but negligibly carcinogenic pesticides from reaching farms to replace older, riskier pesticides. H.R. 1627 resolves the Delaney Paradox in a rational and minimally

SECTION 102. CANCELLATION

We support the changes in FIFRA outlined in H.R. 1627 that will streamline the process for cancellation of potentially dangerous pesticides. The cancellation process should move quickly if a full and complete analysis of the data supports the cancellation of specific pesticide products. Farmers rely on the registration process for safe, effective pest control. If new evidence supports the cancellation of products, that process should move quickly. Much of the integrity of pesticide registration relies on the ability to deal quickly with "bad actors." For these reasons we support new cancellation procedures as outlined in H.R. 1627.

SECTION 201. COLLECTION OF PESTICIDE USE INFORMATION

Farm Bureau policy supports the use of actual pesticide use information, including pesticide records and residue information. We believe that much of this information, when it is used to calculate risks and exposures, clearly demonstrates the safety of our food supply. This section is a necessary portion of a comprehensive food safety package. Safeguards should be taken to protect the confidentiality of the farmer and the farm records.

SECTION 202. INTEGRATED PEST MANAGEMENT

We support the widespread promotion and use of integrated pest management (IPM) as a method of reducing costs, risks, liability and total dependence on farm chemicals. IPM can reduce the risk of output loss, the per-unit cost of production and liability from chemical damages. IPM is a defensible use of pesticides because it focuses use where problems have been identified. However, expanded educational programs are needed to encourage the widespread adoption of IPM, which H.R. 1627 provides. We strongly support the IPM provisions in H.R. 1627.

SECTIONS 302 AND 304. ESTABLISHMENT OF A SINGLE STANDARD

The current conflict between section 408 and 409 of the FFDCA hampers our ability to use science as the basis for pesticide tolerance decisions. Current law is based on 35-year-old science and is no longer applicable. We support the consistent policy towards tolerances outlined in H.R. 1627.

Section 408 of the FFDCA regulates pesticide residues on raw agricultural commodities. Section 409 of the FFDCA regulates pesticide residues in processed foods and allows the EPA to consider benefits to consumers in reaching regulatory decisions unless the Delaney Clause applies. Congress attempted to resolve the conflict between Section 408 and 409 by incorporating into section 402 a provision referred to as the "pass-through" or "flow-through" provision. In spite of Section 402, the differences between FIFRA and FFDCA still present the Environmental Protection Agency (EPA) with a problem on how to regulate pesticides when the Delaney Clause applies. Some pesticides qualify for FIFRA registration and Section 408

tolerances but do not qualify for a Section 409 food additive tolerance under a strict reading of the Delaney Clause.

Under this scenario, the Delaney Clause blocks pesticides that are vital to food production and pose only a trivial cancer risk, but which require a section 409 tolerance. In some cases new, low-risk pesticides are not registered because of the Delaney Clause, while older, higher-risk pesticides remained on the market. The 1987 NAS Report was commissioned to address and resolve these issues. One of the principal recommendations in the report states:

"Pesticide residues in food, whether marketed in raw or processed form or governed by old or new tolerances, should be regulated on the basis of consistent standards. Current law and regulations governing residues in raw and processed foods are inconsistent with this goal."

H.R. 1627 resolves the conflict between section 408 and 409, replaces the Delaney Clause and, consistent with the NAS report, replaces it with a single negligible risk standard.

SECTION 305. TOLERANCES AND EXEMPTION FOR PESTICIDE CHEMICAL RESIDUES

Consideration of Benefits:

Farm Bureau supports the consideration of both the risks and the benefits of pesticides in the evaluation of chemical products. The incorporation in this section of provisions that allow EPA to consider the benefits of pesticide use recognizes the major role pesticides play in maintaining both the quality and quantity of our food supply.

Pesticides allow food to be produced on fewer acres, allowing land that once was devoted to food production to be diverted to other uses. Pesticides allow food to be produced commercially in every state, but since the western United States has typically less pest pressure than the eastern United States, arbitrarily restricting pesticide use, as the Delaney Clause does, is a policy that discriminates against food production in some areas of the country. Shifting production westward cannot solve the problem due to the lack of water, land, labor and other critical resources required for food production. Those resources simply do not exist to accommodate any shift in food production.

To argue that society derives no benefit from pesticide use must also mean that a bountiful food supply contributes nothing to human health. Current law and its risk-only approach to pesticide regulation in the FFDCA does not reflect the contribution of pesticides to our food supply. The consideration of pesticide benefits when a pesticide exceeds the negligible risk standard is a critical improvement in pesticide regulation that Farm Bureau strongly supports.

Negligible Risk

Farm Bureau supports a flexible negligible risk standard. One of the primary lessons from Delaney is that rigid standards do not adapt to changing science. A flexible risk standard recognizes that risk assessment is constantly evolving and improving. This provision will allow the EPA to update its methodology to keep pace with the developing science of risk assessment and we support its inclusion.

Pipeline Provision:

Farm Bureau supports changes in FIFRA that will streamline the process for cancellation of potentially dangerous pesticides. However, if a pesticide tolerance is revoked, we believe that crops that were legally treated prior to cancellation should continue to move through the marketplace unless there is an extraordinary and compelling health reason to the contrary. Without these protections, farmers ultimately bear the entire cost of tolerance cancellations.

National Uniformity:

Farm Bureau supports provisions in H.R. 1627 requiring national uniformity in pesticide residue standards. Current law which allows states and local governments to set pesticide tolerances that are lower than federal standards hinder the interstate movement of commodities. National uniformity also prevents states from claiming that their food is somehow safer, due to more restrictive tolerances. Such claims only serve to frighten and confuse consumers by calling into question federal standards. Farm Bureau supports national uniformity.

International Standards:

The expansion of international trade opportunities is a key component of Farm Bureau policy. The addition of provisions that will allow the EPA to set pesticide tolerances for chemicals that do not have a U.S. tolerance is a positive step that will enhance international trade opportunities for U.S. farmers. Farm Bureau encourages international standards that are based on maximum residue levels established by the Codex Alimentarius Commission. This provision will increase trade while protecting vital food safety interests.

Minor Crop Pesticides

We strongly encourage you to include in this legislation, the provisions embodied in H.R. 967, which you and many others on this Committee have cosponsored. The loss of safe and effective minor crop chemicals is reaching a desperate stage and is critical that this issue be resolved this year, either independently or as part of H.R. 1627.

H.R. 1627 contains a number of fundamental provisions necessary to reform pesticide regulation in the United States which Farm Bureau strongly supports. Do

not be discouraged if you are told that H.R. 1627 will not resolve the food safety controversy. For some critics, there will never be enough science, or safeguards, or restrictions on pesticide use. To them, the issue goes beyond establishing a policy of sound pesticide regulation. At some point you, as policymakers, have to determine what is a prudent public policy. We believe that H.R. 1627, which propels food safety regulation toward science, provides the basis for that policy. We strongly urge your support.



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**STATEMENT OF
 MAUREEN KUWANO HINKLE
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 NATIONAL AUDUBON SOCIETY
 before the
 SUBCOMMITTEE ON DEPARTMENT OPERATIONS AND
 NUTRITION
 COMMITTEE ON AGRICULTURE
 U.S. HOUSE OF REPRESENTATIVES
 AUGUST 2 1993**

Mr. Chairman and members of the Subcommittee, I am Maureen Kuwano Hinkle, Director of Agricultural Policy for the National Audubon Society, a position I have held since 1981. I have testified before the Agriculture Committee on pesticides since the FIFRA overhaul of 1972. Previous to this position, I watchdogged FIFRA after the 1972 passage for the Environmental Defense Fund. I would like to note that members of the National Audubon Society have been concerned about non-target impacts of pesticides since the 1950's.

Unfortunately FIFRA is as contentious and as polarized today as it has ever been. The gridlock that plagues FIFRA has produced the irregular regulation of pesticides, and has contributed to lack of public confidence in regulation of pesticides and in the companies who manufacture pesticides. The new EPA Administrator, Carol Browner, has an herculean job. It is in our best interests, yours and all who are here to testify on pesticides, to try to help you to provide EPA with the authorities needed to do a good job. Continuing gridlock harms everyone. Congress holds the key to unlocking that gridlock.

The proposal we have been asked to comment upon today is H.R. 1627, the Food Quality Protection Act of 1993, co-sponsored by

12 of your 22 subcommittee members. Since introduction of H.R. 1627, the National Academy of Sciences Study on *Pesticides in the Diets of Infants and Children* has been released. We believe that the recommendations made by that scientific body need to be integrated in any legislative change to Federal Insecticide Fungicide and Rodenticide Act (FIFRA) or the Federal Food Drug and Cosmetic Act (FFDCA). The Academy Report found that infants and children are different from the rest of the population both in regard to their vulnerability to toxicants as well as in their patterns of dietary exposure to pesticide residues. (p. 21) The protection of infants and children is necessary and possible and their report specified how such protection can be implemented by EPA, FDA and USDA.

Before we comment on key recommendations of the Academy report that can and need to be integrated into FIFRA and FFDCA amendments, and other provisions of H.R. 1627, we would like to comment on the response of H.R.1627 the National Academy of Sciences Report, *Regulating Pesticides in Food--The Delaney Paradox..*

National Audubon believes that the presence of deliberately added carcinogens in our food and water should be progressively eliminated by the appropriate agencies. The problem has been where and how to make progress as more and more carcinogens are detected each year in our food and water. The Delaney Clause and federal agencies directed to implement it have failed to protect the public from dietary exposure to carcinogens as over a dozen ways have been used to circumvent the Delaney Clause. The 1987 breakthrough study by the Academy demonstrated the extent of carcinogens in our food and articulated ways to reduce this load in a manageable way.

H.R. 1627 responds to the Delaney Paradox by giving EPA the discretion to determine what is a negligible risk for all uses of a pesticide. H.R. 872, the Kennedy-Waxman bill, would establish a uniform standard of risk reduction, including other elements of dietary exposure such as drinking water. The National Audubon Society supports H.R. 872 because it establishes a firm "bright line" of one in a million. We believe that allowing EPA discretion to interpret what is negligible invites political pressure on the Administrator. When Donald Kennedy was Commissioner of FDA in 1976, he pointed out that commissioners are uneasy and increasingly unwilling to decide such policy questions. As one observer put it, "He or she freezes at the wheel." Unless Congress specifies how to calculate risk,

the course of least resistance becomes the norm, and agencies inevitably fail to protect public health adequately unless court action or public outcry ensues.

We also believe that a phased risk reduction scheme is necessary in order to ensure that negligible risk does not become acceptable risk, in other words, gradually raising the level of carcinogens that is deemed acceptable. Requiring a ten to fifteen percent per year reduction in carcinogens would result in meaningful reduction.

We now turn to the recent NAS report which is the first assesment of dietary exposures to pesticides that has focused specifically on infants and children. The report documented how temporal patterns of exposure to pesticide residues in their diet as well as tissue growth, and changes in cell kinetics with age, place children at greater risk than adults from pesticides with carcinogenic potential. Thus, the NAS report recommends that children should be able to eat a healthful diet containing legal residues without encroaching on safety margins.

Because infants and children need special protection due to their sensitivity to pesticides, the Academy Report recommended that **a 1000 fold safety factor should be employed to protect infants and children "when data for toxicity testing relative to children are incomplete."** H.R 1627 affords no specific protection for children, and although consideration of variability of sensitivities of major identifiable groups is required, agricultural benefits are allowed to continue to override health protection for children.

To insure infants and children are not exposed to unsafe levels of pesticide residues, the Academy Report recommended that **tolerances be "based more on health considerations than on agricultural practices."** (p. 8) As the NAS pointed out, the risk-benefit balancing scheme set up in FIFRA "seeks to make possible the beneficial use of pesticides while minimizing their hazards to public health and the environment." (p.17) What has evolved, however, has been a structure through which "it is clearly expected that the anticipated benefits will outweigh the potential risks when the pesticide is used according to commonly recognized, good agricultural practices." (p. 17) The agricultural override has become the norm

for the U.S. population as a whole which leaves protection of infants and children even less protected.

The Academy Report found that "[s]ince many pesticides are applied to more than one crop, residues of a particular pesticide may be found on different foods." Accordingly, the Academy Report recommended that total intake from all foods on which residue[s] may be present should be calculated when estimating exposure of infants and children." (p. 361). For example, captan is used on lettuce and tomatoes, apples peaches and plums. Section 305 of H.R. 1627 which would amend Section 408(b)(1)(D) of the FFDCA would set tolerances for each food. No allowance for treatment of multiple food residues is made.

"Because infants and children are subject to nondietary sources of exposure to pesticides, it is important to consider total exposure to pesticides from all sources combined." (p. 319) H.R. 1627 requires consideration only of food residue of the pesticide, without provision for consideration of drinking water, let alone other non-dietary sources.

The Academy recommended that estimates of total dietary exposure should be refined to consider intake of multiple pesticides with a common toxic effect. H.R. 1627 provides only for consideration of dietary exposure levels to individual pesticide chemical residues.

The Academy Report concluded that "There is no comprehensive data source, derived from actual sampling, on pesticide residue levels in the major foods consumed by infants and children." (p. 260) Existing data on residues for compliance are of limited usefulness for actual exposure evaluations, the Academy Report stated, recommending that EPA "establish a computerized database for pesticide residue data collected by U.S. laboratories." (p. 261) Further, if standardized reporting procedures were developed and adopted, pesticide residue data could be accumulated in a national data bank in a form accessible for future use. Section 201 of title II of H.R. 1627 would only require USDA to survey farmers to produce aggregate data for exposure/benefit. Section 305 would amend 408(b)(1)(E) to require EPA to calculate dietary risk on the

basis of percent of food actually treated with the pesticide and actual residue levels of the pesticide chemical that occur in food. This is to be done in the absence of a system to obtain such data. A survey system is notoriously inefficient. GAO (CED-80-145) concluded that the standard nature of sampling nationwide totals of pesticides . . . can be overstated or understated by 50-100 percent. They are also continually out of date.

In the 102nd Congress, H.R. 3742 came closer to the Academy recommendation. Section 118 of HR 3742 proposed to require USDA to collect and report statistically reliable information on food consumption patterns of food, including subgroups, extent of use of pesticides for crop production, storage, transportation and processing food, representative actual levels of residues, and approximate actual level of human dietary exposure to pesticides. If not available by Jan. 1, 1994, the Theoretical Maximum Residue Concentration (TMRC) would apply.

The Academy recommended that to be of regulatory use, **detection methods must be below established tolerance levels** (p. 214) **In addition, residue analysis methods need to be standardized in a timely manner through an independent review and validation process conducted by a government or professional organization.** (p. 262) HR 1627 has no requirements for quality assurance/quality control.

H.R. 1627 does recognize the need to take into account "major identifiable subgroups of food consumers," as well as the "variability of the sensitivities of major identifiable groups," (Section 305 seeking to amend 408(b)(1)(C)). This reference apparently was intended to apply to infants and children. Nevertheless the Academy identified specific ways to protect infants and children, and a nonspecific reference to subgroups will not be adequate to the many needs documented by the Academy Report.

The preceding recommendations are not the full set of recommendations of the Academy Report, but they serve to demonstrate how infants and children could be protected, and that any legislative change to FIFRA and the FFDCA needs to be address the Academy's findings and recommendations.

Following are comments on other aspects of H.R. 1627.

Section 106. Scientific Advisory Panel

Compensation (travel, hotel and per diem expenses) for 60 scientists to assist review of EPA is very expensive. Such scientists contribute only 2-3 day periods, and although respected and well credentialed, adequate review is seldom possible. Of all the ways EPA could benefit from scientific help, the SAP has not proved to be as helpful as anticipated when authorized in 1975. New ways need to be explored. For example, it would be a better expenditure of taxpayers money to hire first rate scientists to *work at* EPA, even for two year periods, so that the agency could have the benefit of good scientists over a period of time. NIH provides fellowships. EPA could establish a similar program. Scientific societies could be encouraged to select the best young scientists to work for the agency through such a program. The agency could also encourage sabbatical leave for tenured professors to work with the agency.

Section 202. Integrated Pest Management

This section would require EPA and USDA to research, develop, and disseminate IPM and other methods that enable farmers to reduce or eliminate pesticides that pose greater than negligible risk to humans, emphasizing minor crops and foods essential to a balanced, healthy diet. Limiting IPM to minor crops, those pesticides that pose greater than negligible risk or those essential for a balanced diet is tantamount to handicapping the farmer who basically needs IPM for all crop production. IPM should not be limited even more than it already has been.

Sec. 305. Tolerances and exemptions for pesticide chemical residues,

Sec. 408(b)(4)--International standards.

This section would require the Administrator to adopt a Codex maximum residue level (MRL) or set forth in the Federal Register the reasons for not adopting the MRL. This would in effect require EPA to accept the Codex system or state the reason why.

Codex was set up in 1962 to ensure fair trade practices in food standards not limited to pesticide residues, but extending to hygiene, contaminants, additives, etc. Since some countries had no food control, it was necessary to bring them up to a norm. The U.S. is not the most stringent. But there are several differences between Codex

and U.S. tolerances. Cancer classification is different with respect to whether or not the substance is genotoxic and what portion of the commodity is tested. There are differences in that Codex uses indicator compounds and what constitutes "good agricultural practices."

Codex is not the way to "protect the health of United States' consumers" Codex does not take into account consumer protection. Nor is total dietary intake considered, let alone the special protections of infants and children and other subpopulation groups.

Section 408(l) National Uniformity of Tolerances

Section 408(l)(4) State Authority would prohibit any state or political subdivision from establishing or enforcing any tolerance unless the limit was identical to the Federal tolerance. Sec. 408(l)(5)(C) allows a petition under which the state or political subdivision would have to prove (i) compelling local conditions, (ii) no interstate commerce "burden," and (iii) would not "cause any food to be in violation of Federal law." Both section iii and the proposed Sec. 408(l)(6) would prevent any action. The latter section would prevent any state or political subdivision from enforcing a tolerance if the *application* was legal unless the state proves that consumption of such food "will pose an unreasonable dietary risk to the health of persons within such State."

In effect these provisions would prevent a situation such as the findings in 1981 of EDB in muffins, pancake mixes and the like. When a TV station did its own analysis of foodstuffs on grocery store shelves and found residues of EDB, certain States took action before EPA did. Several states established tolerances lower than EPA's, which allowed commodities with EDB residues to be seized in those states. If these states had been prohibited from acting, EPA would have taken its normal time in reviewing EDB. I was with EDF when we petitioned EPA in 1975 to conduct a special review of EDB because it caused metastatic stomach tumors in mice after only 10 months instead of the usual 18-24 months. EDF renewed the petition in 1978 when EDB residues were found in apples and wheat. EPA was still reviewing EDB in 1981, by that time also found in groundwater, when detections of EDB in groceries was televised.

What the proposed sections 408(l)(C) and (6) would do is to prevent a state from protecting its citizenry as it sees fit. If a state

agency detects EDB residues in commodities being marketed, even though they thought them to be unsafe, they would have to prove "compelling local conditions" whatever that is, and could not cause the food to be in violation of the Federal tolerance. Further, as long as the application of pesticides was legal, even if detectable levels were found to be questionable, the state would have to prove that consumption of that food while it's available, would "pose an *unreasonable dietary risk* to the health of persons within [that] state." (emphasis supplied) Every state from now would have to accept the tolerances dictated by EPA as the final word.

This prohibition, together with the way the Federal EPA would be given open-ended discretion to determine what is negligible risk is tantamount to deregulation of pesticides.

Mr. Chairman, and members of this subcommittee, in the last hearing at which we testified, we were asked by Steve Gunderson what our agenda is so he could figure out if there is any reason for him to put time on FIFRA in this congressional session. Many diverse groups met together putting together an agenda that was announced on June 25th. It is, as could be expected, different from H.R. 1627. Nevertheless, it constitutes our best judgment of what is needed to protect all interests--consumers, infants and children, labor, environmental and agricultural.

In conclusion, at the last hearing we testified at, there was doubt expressed as to the connection between chemicals in the environment and cancer causation. I have attached to this statement, a table of industrial agents associated with cancer in animals and/or humans. I think this table shows that what you decide for FIFRA directly impacts exposure of the U.S. population as a whole to environmental carcinogens. The table is from a book, *Cancer, the Misguided Cell*, by David M., Prescott, Distinguished Professor of Molecular, Cellular and Developmental Biology at the University of Colorado, and Abraham S. Flexer, also at the University of Colorado.

We have not commented on all parts of H. R. 1627, as we understand that the Administration is working on a proposal that, as a consensus document among the relevant agencies, should be the starting point from which all parties can proceed in September to work out agreement. For the above reasons, we believe that H.R. 1627 should be deferred to be considered with alternative proposals.

(Attachments follow:)

David M. Prescott
UNIVERSITY OF COLORADO

&

Abraham S. Flexer

CANCER

The Misguided Cell

SECOND EDITION


 SINAUER ASSOCIATES INC.
PUBLISHERS
Sunderland, Massachusetts

TABLE 4. Industrial agents associated with cancer in animals and/or humans.^a Asterisks denote forms of cancer caused in humans by the agent.

Substance	Occupational Exposure	Kind of Cancer
Asbestos	Asbestos miners; asbestos textile makers; auto brake repairers; cement mixers; construction workers; cutters and layers of water pipes; insulation cord makers; insulators; shipyard workers	Lung*, esophagus*, stomach*, large intestine
Coke-oven emissions	Coke-oven workers	Lung, kidney
3,3'-Dichlorobenzidine	Pigment makers; polyurethane workers	Multiple sites including bladder
4-Dimethylaminoazobenzene	Research workers	Liver
4,4'-Methylene-bis(2-chloroaniline)	Elastomer makers; epoxy resin workers; polyurethane foam workers	Liver, lung
α -Naphthylamine	Chemical synthesizers; dye makers; rubber workers	Bladder*
β -Naphthylamine	Research workers	Bladder*
2-Acetylaminofluorene	Research workers	Bladder, liver
4-Aminodiphenyl	Diphenylamine workers; research workers	Bladder*, liver, breast, colon
4-Nitrobiphenyl	Research workers	Bladder
Benazidine and its salts	Biochemists; dye workers; medical lab workers; organic chemical synthesizers; plastic workers; rubber workers; wood chemists	Liver, ear, intestine, bladder*
β -Propiolactone	Plastic makers; chemists; disinfectant workers	Skin, stomach, liver
Auramine	Dye makers	Bladder*, liver

TABLE 4. (Continued)

Substance	Occupational Exposure	Kind of Cancer
Magenta	Dye makers	Bladder*
Chloroprene	Duprene and neoprene makers; rubber makers	Skin
Trichloroethylene	Dry cleaners; drug makers; dye makers; mechanics; printers; shoe makers; soap makers; varnish workers; many others	Liver
Carbon tetrachloride	Firemen; fluorocarbon makers; ink makers; insecticide makers; lacquer makers; rubber workers; wax makers; others	Liver*
Chloroform	Chemists; drug makers; polish makers; solvent workers; silk synthesizers; others	Liver
Acrylonitrile	Acrylic fiber makers; fumigators; plastic product resin makers; textile workers	Colon*, lung*
Ethylene dichloride	Adhesive makers; agricultural workers; Bakelite processors; camphor workers; dry cleaners; furniture finishers; petroleum refinery workers; plastic workers; textile cleaners; others	Stomach, skin, blood vessels, breast, uterus, lung
Mustard gas	Mustard gas workers	Lung*, larynx*
Wood dust	Cabinet makers; carpenters; furniture makers; sawmill workers; wood workers	Nasal cavities and sinuses*
Leather dust	Boot and shoe manufacturers and repairers	Nasal cavities and sinuses*

(continued)

TABLE 4. (Continued)

Substance	Occupational Exposure	Kind of Cancer
Arsenic compounds	Metal industry workers; leather workers; painters; petroleum workers; many others	Lung*, skin*, liver
Chromium and chromates	Electroplaters; gas workers; metal workers; photoengravers; textile workers; welders; others	Lung*, nasal sinuses*
Vinyl chloride	Organic chemical synthesizers; polyvinyl resin makers; rubber workers	Skin, liver*, lung*, brain*, bone
Chloromethyl methyl ether	Organic chemical synthesizers	Lung*
Bis(chloromethyl) ether	Ion-exchange resin makers; lab workers; organic chemical synthesizers; polymer makers	Nose, lung*
Ethyleneimine	Effluent treaters; organic chemical synthesizers; paper makers; textile workers; polyethyleneimine makers	Kidney, liver, lung
N-Nitrosodimethylamine (dimethylnitrosamine)	Dimethylhydrazine makers; nematocide makers; solvent workers	Kidney, lung, liver
Benzene	Adhesive makers; burnishers; detergent makers; dry battery workers; dye makers; furniture finishers; glue makers; petrochemical workers; putty makers; rubber makers; welders; artificial leather makers; shoe workers; others	Leukemia*

TABLE 4. (Continued)

Substance	Occupational Exposure	Kind of Cancer
Soots, tars, oils	Cable layers; coal, gas, coke, petroleum industry workers; coal tar and pitch workers; electrical equipment workers; waterproofers; wharfmen; wood preservers; others	Skin*, scrotum*, lung*, bladder*
Isopropyl oil	Isopropyl alcohol makers	Respiratory tract*, sinus*
Organochloride pesticides	Agricultural workers; insecticide manufacturers	Liver
Polychlorinated biphenyls	Wood preservers; rubber workers; herbicide makers; lacquer makers; paper treaters; many others	Liver
Aniline derivatives	Bromide workers; coal tar workers; disinfectant makers; dye workers; ink workers; leather workers; perfume makers; plastic workers; rocket fuel makers; rubber makers; varnish workers; others	Bladder
Beryllium	Metal workers; miners; nuclear reactor workers; plastic and ceramic workers; many others	Lung*
Iron oxides	Smelters; metalizers; welders; stainless steel makers; steel foundry workers	Respiratory tract*
Lead	Battery workers; brass foundry workers; ceramic makers; glass makers; lubricant makers; painters; plumbers; others	Kidney

(continued)

TABLE 4. (Continued)

Substance	Occupational Exposure	Kind of Cancer
Nickel and compounds	Battery makers; ceramic makers; dyers; foundry workers; paint makers; many others	Lung*, nose*
Selenium and compounds	Copper smelters; glass makers; pesticide makers; plastic workers; rubber makers; textile workers; others	Liver
Cadmium salts	Cadmium industrial workers	Prostate*, lung*
N-Nitrosomorpholine	Rubber and tire makers	Liver

death sentences will not stop at political borders, and they will persist for many generations.

There Are Many Other Sources of Environmental Carcinogens

Dyes are usually organic molecules, and some of them have chemical properties that make them suspect as chemical mutagens or carcinogens. Indeed, aniline dyes derived from coal tars were among the first human chemical carcinogens discovered; they are potent inducers of bladder cancer. Organic dyes are widely used, and they occur in many parts of the human environment. The dye Butter Yellow is a powerful inducer of liver cancer in animals. Addition of this dye to food (primarily butter and margarine) was discontinued in the United States many years ago. The use of Red Dye No. 2 in food and drink was banned in 1976 by the federal government because of evidence that it causes cancer in laboratory animals. Other, quite similar dyes remain in use, because their carcinogenicities have yet to be specifically established for animals.

National Coalition Against the Misuse of Pesticides

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STATEMENT OF
JAY FELDMAN, EXECUTIVE DIRECTOR
NATIONAL COALITION AGAINST THE MISUSE OF PESTICIDES
BEFORE THE
SUBCOMMITTEE ON
DEPARTMENT OPERATIONS AND NUTRITION
COMMITTEE ON AGRICULTURE
U.S. HOUSE OF REPRESENTATIVES

August 2, 1993

Mr. Chairman and members of the Subcommittee. I am Jay Feldman, Executive Director of the National Coalition Against the Misuse of Pesticides (NCAMP), a national, grassroots, membership organization, founded in 1981. NCAMP represents community-based organizations and a range of people seeking to improve protections from pesticides and promote alternative pest management strategies which reduce or eliminate a reliance on pesticides. Our membership spans the 50 states and groups around the world. Thank you for the opportunity to address the Subcommittee today as a part of the process of working with you and the staff to address serious problems resulting from inadequate government regulation of pesticides and food safety, and promotion of alternative methods of pest management.

We appreciate the opportunity to present our comments on H.R. 1627, *The Food Quality Protection Act of 1993*, and other relevant topics in the FIFRA/FFDCA policy making process. This hearing presents the Subcommittee with the opportunity to evaluate this legislation in the context of the need for overall reform of the *Federal Insecticide, Fungicide and Rodenticide* (FIFRA) and a strengthening of the *Federal Food Drug and Cosmetic Act* (FFDCA). In general, we are troubled by the approach adopted in H.R. 1627 because, in our view, it mistakenly adopts the notion that pesticides are too stringently regulated at a moment when the National Academy of Sciences (NAS) report, *Pesticides in the Diets of Infants and Children*, concluded that, "The federal government should change some of its scientific and regulatory procedures to afford infants and children greater protection from possible adverse health effects of pesticides in their diets. . . [and] advises the government to consider all sources of exposure —dietary and non-dietary when

assessing risks to children's growth and development."¹ This is the most recent, but not the only, report that reaches this conclusion and other conclusions about deficiencies in the protections afforded both pesticide users and the public.

I. The safety standard in FIFRA must be improved

As an illustration of H.R. 1627's effect of maintaining a weak safety standard, as opposed to improving public protections along the lines of the NAS report recommendations, I point your attention to the provision in the bill which allows for informal rulemaking to regulate pesticides "to the extent necessary to assure that the pesticide, when used in accordance with widespread and commonly recognized practice, does not generally cause unreasonable adverse effects on the environment" [Sec. 102, Cancellation (b)(1) and (b)(9), at p. 2 and 12]. While this provision restates the FIFRA safety standard and the standard for cancellation and change in classification, it is outdated in not recognizing the need for protecting sensitive population groups and reducing pesticide use in our society. In fact, if incorporated into FFDCA, as proposed by H.R. 1627 [Sec. 305, Tolerances and Exemptions for Pesticide Chemical Residues, Sec. 408(b)(2)(F), at p. 36], it would represent a severe weakening of our food safety law. The Committee on Pesticides in the Diets of Infants and Children, which authored the NAS report, found that the current application of risk-benefit analysis under the "unreasonable adverse effects" standard in FIFRA, is not adequately protective. We urge the Subcommittee to follow the lead of other committees of Congress and adopt a "will endanger" standard, allowing EPA to act on the basis of risk information.

Inherent in the "will not generally cause unreasonable adverse effects standard" in FIFRA and H.R. 1627 is the assumption and belief that pesticides have benefits which must be weighed against their risks. And yet, H.R. 1627 allows to stand the provision in FIFRA which permits EPA to waive requirements to establish product efficacy. An efficacy waiver is in place now for all pesticides except disinfectants. Section 3(c)(5) of FIFRA states, "In considering an application for the registration of a pesticide, the Administrator may waive data requirements pertaining to efficacy, in which event the Administrator may register the pesticide without determining that the pesticide's composition is such as to warrant proposed claims of efficacy." Similarly, the law does not require performance data and thus problems with a pesticide, such as the fungicide Benlate DF -- tied by farmers in Florida and many of other states to billions of dollars of devastating crop damage-- would not show up in EPA's review. Neither would information about pest resistance, now widespread in insects, weeds and rodents, or secondary pest infestations. All these factors affect the ability of a pesticide to perform as

¹Press release, "Changes Needed To Protect Children From Pesticides In Diet," National Research Council, National Academy of Sciences, June 27, 1993.

intended and thus deliver a benefit.

II. Opportunities for reform now exist

Our testimony before this Subcommittee in June on the status of pesticide reregistration contained some general comments on the historical opportunity that we now face with regard to pesticide policy reform. After working with this Subcommittee for over a decade, we believe that this is the case because of general public and pesticide user recognition in the country that pesticides are a serious public health and environmental problem; that dependency on pesticides for the production of food and the control of structural and lawn and garden pests must be reduced dramatically and eliminated where possible. There is increased general understanding that pesticide use has secondary environmental and economic impacts, which some researchers have totalled at \$8 billion annually.²

III. Legislation on food safety must be broadened to control food production impacts on health and the environment

The flooding in the midwest along the Mississippi and its tributaries has raised concern at the U.S. Geological Survey (USGS) about the effects of pesticide runoff on water quality. This is not a new concern in the midwest, but one that brings a heightened interest level because of the flooding. Studies by USGS in 1989, 1990 and 1991 have shown that pesticides like atrazine have been flushed off agricultural lands during late spring and early summer rainstorms, "producing a seasonal 'pulse' of high concentrations of

²Pimentel, David et al., "Environmental and Economic Costs of Pesticide Use: An assessment based on currently available U.S. data, although incomplete, tallies \$8 billion in annual costs," *BioScience*, Vol. 42, No. 10, November, 1992, pp. 750-760. The authors find that, "If the full environmental and social costs could be measured as a whole, the total costs would be significantly greater than the estimate of \$8 billion a year. Such a complete long-term cost/benefit analysis of pesticide use would reduce the perceived profitability of pesticides." To arrive at their total, the authors calculate the following yearly costs (in millions of dollars): public health impacts, \$787; domestic animal deaths and contamination, \$30; loss of natural enemies, \$520; costs of pesticide resistance, \$1400; honeybee and pollination losses, \$320; crop losses, \$942; fishery losses, \$24; bird losses, \$2100; groundwater contamination, \$1,800; and government regulations to prevent damage, \$200. The authors conclude that society pays these environmental and public health costs annually.

pesticides in streams and reservoirs," according to USGS.³ At the same time, the NAS report found that, "Studies of dietary intake should include drinking water and water added to foods, because water constitutes a large portion of an infant's or child's diet."⁴ According to Don Goolsby, a hydrologist who has been studying water quality in the Mississippi River, "Because an estimated 200-300 million pounds of herbicides are applied annually to control weeds in farmland in the midwestern United States, it's important to find out what the impact of flooding on water quality will be."⁵ This situation and the continual runoff of pesticides raises the need to address pesticides in the context in which they are used and consumed, from application rates to food residues. There are other issues to address as well, such as farmworker protection and the effects of pesticide drift. To address one without the other will only undermine the ability to develop a policy protective of public health and the environment.

As presented in our June statement to the Subcommittee, the public and significant numbers of people in the pest management community, both farm and urban, will support an aggressive agenda that moves this country away from pesticide-dependent pest management and significantly reduces our country's reliance on toxic materials in the form of pesticides. We can do this with the recognition that it will not happen overnight, but that it will happen soon. We can do this through the setting of a national goal of reducing pesticide reliance in pest management systems. And we can accomplish it with our country's ingenuity and spirit.

Over its twelve-year history, NCAMP has developed a broad, bipartisan coalition composed of those who have experienced the problems associated with pesticides and the benefits of alternative pest management practices that are not reliant on pesticides. People and their organizations that are a part of NCAMP come from both an urban and rural perspective, farm and nonfarm. What joins the coalition members together is a concern about the widespread use of pesticides that has resulted in adverse health and environmental effects and property damage. These are not abstract problems, but real ones that demand government intervention.

IV. Protect and develop strong safety and environmental standards

Instead of defending a U.S. food production system that pollutes,

³Press release, "Water Quality Studies of Mississippi River Flood Waters Underway by USGS," U.S. Geological Survey, Department of Interior, July 29, 1993.

⁴Press release, NAS.

⁵Press release, USGS.

poisons and contaminants, we believe that policy makers should engage in an all out effort to help farmers wean themselves of their dangerous chemical fix. We should not accept the risks, especially when there are less risky alternatives available to achieve pest management goals. We should not institutionalize unnecessary risks without investing in the research to help bring about the adoption of alternative, sustainable methods of pest management. We must stop thinking about food safety in a vacuum of residue rhetoric and tolerance setting and start addressing the issue of food safety in a holistic manner, by considering the long-term need for chemicals in sound agricultural systems that are not only better for the food consumer, but protective of farmers, farmworkers, wildlife and the environment. In calculating risk assessments, the NAS committee says, "Regulators should consider all sources of dietary and non-dietary pesticide exposure."⁶

To start, we must set a date by which we will remove from the market cancer causing pesticides used in food production. Until that date, we should prepare for the transition to alternative methods of pest management that do not rely on pesticides. When alternatives are identified, they should be adopted immediately in place of the pesticide. When alternatives do not exist, research into alternatives should be initiated immediately and phased-in over a period not to extend beyond the year 2,000.

This position grows out of the belief that public policy should err on the side of public health and safety, not rhetoric that is based on uncertainty of safety thresholds and poor pesticide exposure assumptions. Basic to this position is the fact that the Delaney Clause of FFDCA is based on sound science, with human experience confirming laboratory animal studies on cancer effects.

In the year since the Ninth Circuit court decision upholding the Delaney Clause, the provision has been called outdated and anachronistic by politicians and industry interests. However, the law is based on the scientific understanding that we cannot prove the level at which a cancer causing substance initiates a cancer effect, although we can determine that a chemical is a carcinogen. This distinction stems from the fact that high dose animal experimentation can tell us that a chemical causes cancer, but it does not tell us the low dose point at which the chemical has no effect. Given that carcinogens have delayed or long-term effects, animal experiments have never been able to replicate the time period and low dose. For all the criticism, the high dose method has yielded impressive results, proving accurate in the vast majority of cases where chemicals are known through epidemiological studies

⁶Press release, NAS.

to cause cancer in humans.⁷ There is no scientific basis for suggesting that any carcinogenic exposure represents a "trivial" or "negligible" risk. The Delaney Clause errs on the side of public health protection and rightly so.

Those arguing the Delaney Clause's demise would have it replaced with a "negligible risk" standard, as proposed by H.R. 1627 [Sec. 305, Tolerances and Exemptions for Pesticide Chemical Residues, Sec. 408(b)(2)(D), at p. 35]. The "negligible risk" standard is steeped in risk assessment methods that are filled with uncertainties and miscalculations as to sensitive population groups, such as children and elderly, average body weight, consumption patterns, and other exposures affecting the total toxic load that any one individual already carries.

Consider what the U.S. General Accounting Office (GAO) told the U.S. Congress in February of last year. Investigators for GAO concluded that EPA does not have adequate exposure data to make safety decisions. In its testimony, GAO indicated that EPA did not have reliable data on the quantity of pesticides used on food crops. The statement went even further to say that inadequate knowledge supports risk estimates. According to GAO,

Our recent work on EPA's use of USDA's Nationwide Food Consumption Survey illustrates how inadequate knowledge may affect pesticide risk estimates. To establish safe levels of pesticide residues in or on food, EPA estimates dietary exposure to pesticide residues using data from USDA's survey, which is conducted every 10 years. However, we found that EPA's estimate of potential human exposure to pesticide residues in food is uncertain because these surveys are flawed. For example, our review of USDA's 1987-88 survey found that it was not representative of the U.S. population because the response rate was too low. To compensate for this deficiency, EPA is using the older 1977-78 survey data to estimate food consumption, but this survey may not reflect the current eating habits of Americans. Moreover, neither the 1977-78, nor the 1987-88 Nationwide Food Consumption Survey sampled subpopulations, such as infants and pregnant females, in numbers large enough to permit precise estimates of their dietary exposure and, hence, of risks to them from pesticide residues.⁸

In the end, the Delaney Clause offers our nation an opportunity to stop the use of deadly pesticides, recognizing some simple facts:

⁷Wilbourn, J. et al., "Response of experimental animals to human carcinogens: an analysis based upon the IARC Monographs programme," *Carcinogenesis*, vol. 7, no. 11, pp. 1853-1863.

⁸GAO, *Food Safety: Difficulties in Assessing Pesticide Risks and Benefits*, February 26, 1992, GAO/T-RCED-92-33, p. 7.

- *Alternatives work.* Soybean growers in Practical Farmers of Iowa have replaced the cancer causing herbicide alachlor with tillage systems and planting techniques to shade out weeds. They eliminated one of the 32 carcinogenic pesticides announced by EPA while maintaining productivity and profitability --at yield higher than the state average and an average savings of at least \$11.00 an acre.⁹

- *Risk assumptions belie reality.* The risk assessment strategies proposed to replace Delaney ignore the fact of multiple chemical exposure. For example, 11 of EPA's 32 carcinogenic pesticides are registered for use on apples, 10 on grapes. Assessing the risk from a piece of fruit, a plate of food, and three meals a day is beyond the grasp of the proposal. Worse yet, there is no attempt to aggregate the risk of nonfood exposure to the very same pesticides, which are widely used on lawns, in parks and school yards, or the risk to those at highest risk.

- *Chemical-intensive agriculture is costly to consumers.* What we don't pay at the grocery store, we pay in health and pollution costs and losses to farmers caused by pest resistance to pesticides --all to the tune of \$8 billion a year, according to Cornell University researchers.

Neither the nation nor the world will starve without the 32 cancer causing pesticides EPA has identified.¹⁰ Instead of regulating carcinogenic pesticides into food production with flawed safety standards, a national effort must invest in assisting chemical-intensive farmers to shift away from pesticide dependency to sustainable practices. The Congress and the Clinton Administration have an opportunity to lead the way to enforce existing law and ensure the orderly phase-out of cancer causing pesticides. The way to do this is through the protection of the Delaney Clause.

V. Negligible risk is not founded in good science -- it translates to unacceptable and unnecessary risk.

Because it is so central to the debate ongoing in Congress and questions related to the future health of our nation, I will focus substantial attention in this statement on the negligible risk standard and illustrate a number of its deficiencies.

⁹Summary, Practical Farmers of Iowa, Weed Control Trials, Annual Membership meeting, December, 1989.

¹⁰Kasper, John, Note to Correspondents, "Pesticide Uses Potentially Affected By Revocation of All Section 409 and Corresponding 408 Tolerances," EPA, February 2, 1993.

It must be recognized that the "negligible risk" standard --central to H.R. 1627-- is based on extremely imperfect methods of predicting risk, collectively known as risk assessment. It is the inadequacies of these predictive tools that require our critical examination in order to evaluate the validity of the concept as a whole.

At a time when cancer plagues our nation, dramatic steps must be taken to prevent avoidable exposure to carcinogenic materials. Cancer is a killing and disabling disease of epidemic proportions. Cancer now strikes one in three persons and kills one in four." Scientific consensus contends that cancer is mainly caused by exposure to causative agents in the environment and chemically-induced cancer has been well-demonstrated. We are exposed to a wide range of carcinogens in our environment, some of which occur naturally, but many of which are a direct result of an industrialized society. Addressing the cancer threat requires elimination of unnecessary and preventable exposures.

Attempts at managing risks under a "negligible risk" policy ignore the fact that the last three decades have confirmed the scientific basis of the Delaney clause and our inability to quantitatively define carcinogenic risk.

- The Delaney principle is still the best scientific standard for cancer control. Cancer mechanisms are not completely understood, but all scientifically acceptable theories preclude measuring or predicting a "safe" level of exposure to any carcinogen below which no individual or population group will develop cancer. Recognition of this forms the basis of the Delaney clause standard of no additional cancer or "no induction of cancer."

As a substitute for the Delaney clause, H.R. 1627 proposes to establish a "negligible risk standard," tied to an "acceptable" incidence of cancer. Ratification of this new standard, already adopted by the Environmental Protection Agency (EPA) in an interpretive rule in October, 1988 (53 FR 411050) and successfully challenged in court, undermines long term public health and safety.

- Negligible risk is too crude a measure. A negligible risk formulation relies on risk assessment modeling, a crude tool containing numerous uncertainties which make it inadequate for predicting potential hazards to people ingesting carcinogens. Depending on the assumptions and models used, calculated risks can vary by orders of magnitude. Risk assessment can not accurately yield thresholds for cancer effects in humans. At best it can give us indications of relative risks.

¹Epstein, S.S., "Losing the War Against Cancer: Who's to Blame and What to Do About It," *International Journal of Health Services* 20(1):53, 1990.

It has become accepted practice to use animal cancer bioassays in which animals are exposed at doses that approximate the animal's maximum tolerated dose. This is done in order to maximize the likelihood of a positive effect, using experimental animal group sizes that are manageable logistically and economically. Central to predicting the toxic effects of a substance is the process of generating a graphical dose-response curve. The shape of such a curve may vary from chemical to chemical and even for a single chemical is not likely to be linear over its entire range. However, scientists plotting tumor incidence against dose of the putative carcinogen are plotting data points relevant to the high end of the curve where doses are large. In point of fact, the validity of extrapolation down to low doses is not easily verifiable, and may not accurately predict the shape of the curve at that end of the scale.

The One-Hit model used by EPA and widely considered our most conservative model, assumes that tumor yield graphed against dose will be linear in the low-dose range (based on mathematical proofs). However, a review (Bailar, et al., 1988) indicates that it is less conservative as popularly assumed.¹² Using data from 1212 bioassays on 308 chemicals tested by the National Toxicology Program, it was found that in a small percentage of cases the mathematically generated curve may deviate significantly from the actual animal bioassay results. This occurs more frequently than expected by chance, resulting in significant under-estimation of risk by this supposedly extremely conservative technique.

- **Limitations exist in estimating carcinogen potency.** An essential element in cancer risk calculation, carcinogenic potency is derived by calculating the slope of the curve graphed by plotting tumor yield against dose in animal bioassays. These slopes, which EPA calls Q*-values, may be derived from a series of carcinogenicity bioassays and averaged to get an overall potency figure. The artificiality of this process is especially troublesome when experimental data do not correspond well to linear dose-response models, for example with many Class C (possible human) carcinogens. Also, potency is alterable by a host of external factors. As Maugh stated in a 1978 review, "Significant differences in the observed potency of carcinogens in laboratory animals can be obtained, for example by exposing the animals to chemical agents that stimulate or depress drug-metabolizing enzyme systems; by modification of the animals' diet; by changing the hormonal balance of the animals; and by stressing the animals in various ways, such as by increasing the number in a cage."¹³ Most importantly, the influence of multiple chemical

¹²Bailar, J.C., et al., "One-Hit Models of Carcinogenesis: Conservative or Not?," *Risk Analysis*, 8(4):485-497, 1988.

¹³Maugh, T.H., "Chemical Carcinogens: How Dangerous Are Low Doses?," *Science*, 202:37-41, 1987.

exposures is an important issue that current mathematical models are too crude to assess, yet is a reality of human exposure.

• **Limitations exist in estimating exposure.** Exposure calculations are combined with carcinogenic potency values to obtain a cancer risk estimate. Just as artificial as carcinogenic potency estimates, exposure estimates can be derived in several ways, depending on the quality of the pesticide residue data base. Dietary exposure estimates tend to generalize risk over an "average" situation or population, away from the consideration of particular situations and individual sensitivities. This oversimplification is dangerous, since the simple inclusion of exposure figures for sensitive sub-populations within the overall average exposure calculation does not in fact address the particular hazard that a sub-population might face. Rather, it obliterates it from conscious consideration. As stated by Hattis, 1989, "Should the analyst take pains to uncover and disclose the distribution of the risk among the population? A 10^{-6} risk of death from a specific hazard for an aggregated group might translate into 10^{-2} for a particularly at-risk subset--Holdren (1982) cites possible differences in the distribution of risk between rich and poor, the medically susceptible and the population as a whole, and between those who have a voice in the acceptance of risk and those who do not."^{14,15}

In addition to these problems, as mentioned above, risk assessments are limited to the effects of exposure to a single toxic agent. They do not consider "plate-of-food" risks and thereby underestimate the additive risk from ingesting multiple carcinogens.

• **Differences in professional judgement led the state of California to different safety findings from EPA.** These issues are further clouded by differences in professional judgment. The data used to register pesticides continues to be generated by registrants, it is still not peer-reviewed, and it is still not generally available to independent scientists or the public. Recently, State Senator Nicholas Petris (D-CA) challenged the accuracy of EPA's data evaluation program, making public a California Department of Food and Agriculture (CDFA) report citing many differences of opinion between CDFA scientists and EPA evaluators of the same pesticide registration data. CDFA review found disparities in 58 of 99 active ingredients, or 59% of the time, while EPA ascribes most of the disagreements to "differences in professional

¹⁴Hattis, D. and J. Smith, "What's Wrong With Risk Assessment?," *Biomedical Ethics Reviews*.

¹⁵Holdren, J., "Energy Hazards: What To Measure, What To Compare," *Technology Review*, April, 1982, pp. 33-39, 74-74.

judgement."¹⁶ This controversy serves to remind us that the EPA review process is not an infallible base on which to build any kind of a cancer risk calculation.

- The negligible risk standard is unacceptable to the public. People have made it clear to us that they do not want to eat, nor do they want their children to eat, carcinogenic pesticides. Growers and eaters agree that the food supply must be safe. The negligible risk standard of safety is not an adequate predictor of safety. The public does not want to be lulled into a false sense of security. For these reasons, we support the establishment of a standard by which society prohibits the purposeful introduction of cancer-causing agents into the food supply and rejects the unproven assumption that these poisons are necessary to a food production system yielding affordable food prices.

- Scientific issues have been neglected in committee hearings. We are troubled that the scientific issues have been neglected in the political debate over the Delaney Clause. There has been virtually no independent scientific debate on "negligible risk," except for testimony submitted several years ago to another committee of Congress by a preeminent cancer researcher, formerly with the Frederick Cancer Research Institute, Dr. William Lijinsky. Dr. Lijinsky raises critical scientific issues and is very concerned and troubled, as are we, about the establishment of a "negligible" or safe threshold for human exposure to carcinogens. To quote Lijinsky,

In view of the small amount of information about the mechanisms by which chemicals give risk to cancer (and the uncertainty about the relevance of that information), it is unwise to permit officials or experts to calculate tolerable or "safe" exposure for humans to carcinogens. All of us are fallible even when armed with sound information. Reliable information about carcinogens is limited almost to whether or not the substance is one.

The kinds of questions raised by Dr. Lijinsky and others are critical in light of the legislation's dramatic long-term safety implications, not only for pesticide control but its potential future application down the road to other toxins in food coloring, dyes and additives.

We urge you to defend and protect the Delaney Clause and adopt language that seeks to phase-out the introduction of carcinogens to the food supply, rather than institutionalize such practice.

In June, a coalition of national environmental, labor and consumer

¹⁶Letter from EPA Acting Deputy Administrator John Moore to California State Senator Nicholas Petris, March 3, 1989.

groups endorsed the *Pesticide Reform Agenda*¹⁷ that calls for the phase-out of cancer causing pesticides and the removal of other pesticides shown to cause other effects such as birth defects, nervous system damage, and other health effects. At the same time, the coalition called for a major national effort to put alternative pest management approaches in place that do not rely on pesticides as soon as possible, but no later than the year 2,000. Over three years ago, in March, 1990, congressional leaders joined with scientists and environmentalists to assail a number of Administration and congressional efforts to repeal the Delaney Clause¹⁸ (statement attached). Instead, the coalition supported the orderly phase-out of pesticides shown to cause cancer in laboratory studies. The move for a phase-out of carcinogenic pesticides has been supported by the public for a long time.

VI. Preemption is undemocratic and unacceptable policy and attacks states' rights

The authority of states to protect residents is essential to decision making in a democracy. It is especially important given the flexibility provided the regulatory agency to engage in risk assessment decision making, with a range of possible assumptions and population groups. H.R. 1627 takes away state authority to set tolerances [Sec 305, amends 408(l)(4), at p. 64]. This is wrong. Federal food safety law, whatever it ultimately looks like, should establish a minimum standard of public health protection. We believe it is inappropriate for the federal government to lock states out of the process of protecting its residents in a manner that is more protective than the federal government. Citizens have a right to act at the state level to protect themselves, their families, and their communities.

We are faced with a federal regulatory system that is failing the American public. EPA has been engaged in a series of controversial risk and cancer classification decisions for the past decade. The public should not have to depend on a system of decision making that has failed to meet its statutory duty to evaluate pesticides and then deny states their basic right to protect the health and welfare of its residents. Pesticide policy has governed a system that has been plagued by inaction and inappropriate action in our view.

¹⁷*Pesticide Reform Agenda: An Agenda for Reform of the Nation's Pesticide Laws*, June 21, 1993.- At the time of its release, the following national groups had signed on: Center for Resource Economics, Consumers Union, Farmworker Justice Fund, Government Accountability Project, National Audubon Society, National Coalition Against the Misuse of Pesticides, Natural Resources Defense Council, Public Voice for Food and Health Policy, Physicians for Social Responsibility, and World Wildlife Fund.

¹⁸Rep. Weiss, Ted and Rep. Conyers, John, *Keeping Cancer Causing Materials Out of the Nation's Food*, U.S. Congress, March 26, 1990.

Given this situation, it would be counterproductive to prohibit states from involving themselves in the difficult task of safety decisions. Historically, states have played a very constructive role in setting standards and contributing to EPA's decision making process, as a result.

VII. Streamline cancellation and suspension procedures

NCAMP has urged a streamlining of the cancellation and suspension process along with others for many years. In joining with our support for the *Pesticide Reform Agenda*, NCAMP has said that cancellation and suspension provisions in the bill as introduced by Rep. Charlie Rose in the last Congress, H.R. 3742, is a good starting point for discussion in this area. In terms of suspension procedures, EPA should have clear authority to suspend a pesticide posing imminent hazards, without first completing a detailed benefits assessment, as required in H.R. 1627. The language in Section 104 [Suspension, at p. 17] makes it difficult for the Administrator of EPA to issue a suspension order, thus undermining the goal of streamlining the process.

This is what the Bush White House had to say about the current cancellation and suspension process:

Currently, the administrative process for removing a dangerous pesticide from the market can take four to eight years. The process begins with an initial determination by EPA that use of the pesticide poses some threat to human health or the environment. If EPA decides to pursue cancellation, a formal administrative process ensues, which includes extensive opportunity for public comment, as well as independent review by a scientific advisory panel and the U.S. Department of Agriculture. That decision can be challenged in a hearing before an Administrative Law Judge. Additional judicial review of EPA's final order is also available. Throughout the whole administrative review and hearing process, the product remains on the market unless EPA finds that it poses and "imminent hazards." Such a finding permits immediate temporary cancellation (suspension) of the chemical, but the current threshold for recognizing an imminent hazard is so high that such a finding has only rarely been made (only three times in eighteen years). Overall, the current mechanism for removing pesticides from the marketplace is cumbersome and confusing.¹⁹

- **The standard that allows for the initiation of a cancellation proceeding is weak and unprotective.** Current FIFRA language, reiterated in H.R. 1627 [Sec. 102, Cancellation (b)(1), at pp. 2-3], which allows the EPA Administrator to initiate informal rulemaking, "to the extent necessary to assure that the pesticide, when used in accordance with widespread and

¹⁹Fact Sheet: President Bush's Food Safety Plan, October 26, 1989.

commonly recognized practice, does not generally cause unreasonable adverse effects on the environment," is exceedingly biased in favor of continued registration of harmful products. Compare this language with that contained in H.R. 3742:

The Administrator may initiate a proceeding in accordance with this subsection if the Administrator determines, on the basis of criteria regarding data and information regarding adverse effects and exposure supplied pursuant to regulations published by the Administrator, that there are prudent concerns that a pesticide may cause unreasonable adverse effects on man or the environment. [Sec. 106 Cancellation or modification of registration (b)(2)]

The language in H.R. 3742, while it could be improved, provides EPA with the authority necessary to act, and act with speed.

- The period of time associated with the cancellation process in H.R. 1627 can be drawn out indefinitely, with room for excessive delays and then judicial review. Contrast this with the provisions in H.R. 3742 which instructs that the Administrator "shall take such steps as are reasonably necessary to allow final action to be taken . . . within a period of 18 months after the publication of the proposed order. . ." [Sec. 106(b)(9)(H), at p. 23]

- Public involvement is critical to the cancellation process. However, H.R. 1627 only authorizes a "registrant, or other interested person with the concurrence of the registrant" [Sec. Cancellation (12)] to petition for an amendment or revocation of a rule. Similarly, "any person who will be adversely affected by such a rule or decision and who has filed comments in the proceeding leading to the rule or decision may obtain judicial review" [Sec. 107, Conforming Amendments (h)(3)] excludes public involvement unless "any person who will be adversely affected" is broadly defined to include the general public.

- Existing stocks of cancelled pesticides should generally not be allowed to be sold off. Once a hazard is deemed unacceptable, it should be discontinued. However, when existing stocks of cancelled pesticides are permitted to be sold off, there should be a finding of no adverse effects with clear findings on: (i) the amount and location of stocks and length of time it will take to use of the material under different utilization rates; and (ii) the impacts on health and the environment on different exposed populations groups. Senator Lieberman's *Pesticide Health and Safety Act of 1991* (S. 1353, introduced in a previous Congress) would amend FIFRA to tighten the existing stock provision. The bill: (i) allows the Administrator to continue sale or use of existing stocks of a suspended pesticide if the Administrator makes a specific finding that the use will not cause significant adverse effects to human health or the environment; (ii) requires existing stocks to bear a label stating

that production of the pesticide has been suspended because of concerns about adverse health and environmental effects; and, (iii) mandates that if the stocks may no longer be sold, the manufacturer must accept return of the pesticide and reimburse the purchaser.

- **Streamline interim administrative review [FIFRA, Section 3(c)(8)]** to ensure adequate special review of hazardous pesticides. Section 3(c)(8), the so-called Grassley-Allen amendment of 1978, provides that the Administrator may not initiate an interim review process, or "special review," "unless such interim administrative process is based on a validated test or other significant evidence raising prudent concerns of unreasonable adverse risk to man or the environment." EPA has read this to require that the agency consider the extent of human and environmental exposure to pesticides prior to initiating the review. Previously, the rebuttable presumption was triggered for chronic toxicity by evidence concerning the properties of the pesticide alone. The registrant was required to rebut the presumption by demonstrating inter alia that human or environmental exposure was so small as to demonstrate that the pesticide's benefits exceeded its risk. Section 3(c)(8) places an enormous burden on an understaffed EPA and should be eliminated. In addition to determining the toxic effects of chemicals, it must also gather evidence of actual exposure to the pesticide before initiating a review.

- **Immediately cancel pesticide registrations based on false, misleading or inaccurate information.** A new section should be added to Section 6 of FIFRA which authorizes the Administrator to immediately issue a notice of intent to cancel a pesticide's registration, or revoke tolerances, if it appears to the Administrator that false, misleading, or inaccurate information has been submitted in support of the registrations or tolerances. If a hearing is held pursuant to the notice, the issues for resolution shall be limited to whether false, misleading or inaccurate information was submitted to the Administrator. This should be completed within a specific time frame, such as 120 days. The history of fraudulent and faulty data supporting pesticide product registrations, from Industrial BioTest Laboratories (IBT) in the 1970's to Craven Labs in the 1990's, supports this statutory change.

- **Public participation in decision making is critical.** Under current law, and extended under H.R. 1627, is a prohibition on public participation in EPA decisions to register a pesticide and set a tolerance [Sec. 305 amending FFDCA Sec. 408(g) Confidentiality and Use of Data, at p. 53]. Although FIFRA now provides for public notice of impending registration decisions, EPA is not required to make the safety tests which form the basis for the decision available to the public until 30 days after the decision is made [FIFRA, Secs. 3(c)(2)(A) and 3(c)(4)]. Legislation should change the provision of FIFRA pertaining to the disclosure of information submitted to the Administrator in support of a pesticide registration. The Administrator should make available to the public in an expeditious manner the data submitted in support of

registration applications, or petitions to establish tolerances. Data should be discloseable subject to the provisions of section 10 of FIFRA, prior to granting registrations or establishing tolerances during the period the Administrator is evaluating the pertinent applications. It is critical that there be public participation in EPA decision making regarding the introduction of toxic materials registered for food production and all other uses.

The proposals in H.R. 1627 fall short of the requirements needed to move the process along expeditiously, to do it in a manner that ensures full open public participation, with health and environmental standards that are protective of public health and the environment.

VIII. Actual residues should not be used for calculating risk unless those levels are established as the enforceable tolerance

If residue assumptions based on "reliable data" of food "actually treated" is to be used to calculate the dietary risk posed to food consumers, as proposed by H.R. 1627 [Sec. 305, Tolerances and Exemptions for Pesticide Chemical Residues, Sec. 408(b)(2)(E) at pp.35-36], the levels must be enforceable. Otherwise, a violative finding that is below tolerance, yet about what was assumed to be the actual for risk calculation purposes, could not be acted on. The system, then, would provide the public with no assurance that it was being protected at the level calculated as "acceptable" by EPA.

IX. Practical methods of residue detection and enforcement are critical

On a positive note, the bill prohibits the setting of a tolerance for chemicals for which there is no "practical method for detecting and measuring the levels of the pesticide chemical residue in or on the food" [Sec. 305 Tolerances and Exemptions for Pesticide Chemical Residues, Sec. 408(b)(3)(B), at p. 37]. It also prohibits the setting of a residue at a level lower than the limit of detection [Sec. 305., amending Sec. 408(b)(3)(C), at p. 38].

X. Drive to uniformity is not warranted

The push toward uniformity with international standards, as established by the Codex Alimentarius Commission, creates an additional burden on EPA that is not called for. "If the Administrator determines not to adopt a Codex maximum residue level, the Administrator shall publish a notice in the Federal Register setting forth the reasons" [Sec. 305. amending Sec. 408(b)(4), at p. 38]. If H.R. 1627 seeks to meet an industry need to establish marketing and testing uniformity, the taxpayer should not be required to pay the costs. If a registrant would like to use data prepared for Codex purposes, it should not be a burden to EPA.

XI. Pesticide reform issues require the attention of the Subcommittee

There are numerous issues that do not fall within the provisions of H.R. 1627, but require attention in the context of improving food safety and public health and environmental protection associated with food production. Many of the issues are included in the *Pesticide Reform Agenda* cited above, and address a range of issues, including a standard for protection of children, labelling of foods containing carcinogens, protection against non-cancer effects, accelerating alternatives, recordkeeping, farmworker protection, whistle blower protection, citizen suit provision, restrictions on the exportation of banned, severely restricted, and unregistered pesticides, and improved penalties and enforcement. Also on our agenda is a need to review and disclose all toxic pesticide ingredients and no longer continue the false distinction between so-called "active" and "inert" ingredients.

XII. Conclusion

We have an opportunity to change the way we regulate pesticides and meet the food production and nutritional needs of the public, while meeting the productivity and profitability needs of those who grow and market food commodities. We have presented to the Subcommittee in the past, most recently in June, our outline for a *Federal Pest Management Act*, which takes a holistic look at pest management and the social and health costs of pesticide dependency. It is an approach quite different than FIFRA and H.R. 1627. H.R. 1627, overall, embraces the business-as-usual approach to pesticide law and asks us to take a narrow look at pesticide use, while lowering standards of protection by calling the risks "negligible." The bill would disempower people and state governments, rather than bring them into the democratic decision making process.

Pesticide policy reform must move us ahead, not backwards because of an unfounded fear that we cannot achieve our pest management and productivity goals. It is difficult to find a person who does not want to achieve the goal of public health and environmental protection, while meeting needs for food production. The question is whether we, as a nation, can afford to maintain a course of dependency on highly toxic pesticides with policies that tinker with flawed risk assessment calculations. We do not think so. We may feel good about what we have accomplished in the short run, but we will have failed our children, future generations, and the sustainability of our planet.

Thank you for the opportunity to share our views with you. We appreciate your attention to critical pesticide problems and look forward to working with the Subcommittee to resolve these problems.

(Attachments follow:)

Congress of the United States
House of Representatives
Washington, DC 20515

KEEPING CANCER CAUSING MATERIALS OUT OF THE NATION'S FOOD

March 26, 1990

We join today in defense of our Nation's health and in defense of a basic scientific principle that has been an integral part of our Nation's food safety law since 1959 — the Delaney Clause. This provision, now under attack from different quarters on a range of issues from pesticides to the color additive red dye no. 3, is undeniably the only sensible and scientifically sound way to regulate cancer materials that might otherwise be intentionally added to the environment.

At a time when our Nation is in the midst of a cancer epidemic, steps must be taken to ensure the prevention of avoidable exposure to carcinogenic substances. The Delaney Clause does this.

For the first time since 1958, new Federal actions would permit the intentional addition of carcinogenic pesticides to processed food. The cancers caused by pesticide residues in food would be "acceptable" or "negligible" under a 1988 Environmental Protection Agency (EPA) regulation and a 1989 government-wide Food Safety Plan. These Executive actions override a law, the Delaney Clause, which was intended to protect the American public when it was adopted in 1958.

Representative Delaney's law was based on sound principle: that there is no way to find an amount of exposure to a carcinogen that can be called entirely safe. Thirty years of research, including an ability to detect far smaller quantities of carcinogens, have not challenged the principle.

In contrast, the new pesticide policies that speak of "negligible" and "de minimis" risk, seek to manage risk at "acceptable" levels. They permit one kind of pesticide residue in or on one kind of food to cause an excess cancer in every 100,000 to one million people. When this level of cancer hazards is added up for the many pesticides found in many foods, it means thousands of extra cancers each year caused by chemicals intentionally added to our diet.

When the EPA and the Food and Drug Administration estimate the effect of the carcinogens in the food, they ignore the exposure to carcinogens that the same people will receive from chemical and radioactive carcinogens in air, water, and the workplace. They also ignore other hazards associated with the same chemical, by choosing to base their decision on carcinogenicity alone.

What about neurologic, behavioral, genetic and reproductive damage done by the same chemicals? They are not accounted for?

We protest the new Administration policies, and similar efforts in Congress, and urge our colleagues and all citizens to oppose actions that seem likely to reverse the growing trend to reduce the introduction of dangerous pesticides into our foods. If the Administration follows its new policies in other areas of public health and environmental protection, new levels of "acceptable" risk will help contaminate our air, water, and food.

The warning signs are evident. Secretary of Health and Human Services Sullivan has said he will seek a repeal of the Delaney law. The Office of Management and Budget has begun to tell scientists who study cancer causation how to define a carcinogen and thus evade application of the Delaney provision.

Now is the time to protest the Administration's refusal to enforce the law and protect the public health. We reject efforts to use the language of science to tell the American people that preventable cancers are now "acceptable" as part of a program of risk management.

Instead, we join in an effort to defend the principle of the Delaney Clause. If cancer-causing pesticides cannot be immediately banned, we support efforts to phase out their use as quickly as possible.

TED WEISS, CHAIRMAN
Human Resources and
Intergovernmental Relations
Subcommittee

JOHN CONYERS, JR., CHAIRMAN
Committee on Government Operations

PESTICIDE REFORM AGENDA

**AN AGENDA FOR REFORM OF THE NATION'S
PESTICIDE LAWS PROPOSED BY
CONSUMER, LABOR, ENVIRONMENTAL,
AND PUBLIC HEALTH ORGANIZATIONS**

June 21, 1993

PESTICIDE COALITION

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Consumers Union
Kristen Rand
462-6262

Friends of the Earth
Velma Smith
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National Audubon Society
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Public Voice for Food and Health
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Government Accountability
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PESTICIDE REFORM AGENDA

I. Introduction.

Over the last 30 years since the publication of Rachel Carson's Silent Spring, pesticide use has substantially increased, and the adverse effects of pesticides have continued apace. More pests are becoming resistant to pesticides, and farmers are not being given the information and tools they need to make the transition away from risky pesticides towards safer alternative pest management techniques. And despite ever-increasing public understanding of the potential dangers of pesticides, public health still is put in jeopardy from pesticides in foods, drinking water, air, and other media, farmers and farm workers continue to be poisoned and their long-term health endangered, and fish and wildlife continue to be threatened by pesticide poisoning and chronic effects. Therefore, environmental, farm worker, labor, public health, and consumer organizations propose a legislative platform to strengthen and modernize the nation's archaic and inefficient pesticide program and promote the development of alternatives to hazardous pesticides. Other important administrative reforms can be accomplished at this time without statutory change.

II. Principles to Ensure Food Safety

The American public has repeatedly made it clear, in polls taken by industry groups and independent pollsters, that there is widespread concern regarding pesticide residues in foods. Studies on the risks posed by pesticides in foods reinforce the conclusion that this public concern is often well-founded. Thus, we propose below a pesticide and food safety reform agenda.

A. Phaseout of Tolerances for Carcinogenic Pesticides.

Cancer-causing pesticide residues on foods should be phased out over a reasonable time period. There are substantial uncertainties inherent in quantitative risk assessment due to data gaps and methodological problems that necessitate a phase out. Risk assessments used to determine, for example, whether a pesticide supposedly poses a "one in a million risk," do not address cumulative risks from the same pesticide from all sources of exposure, and completely fail to consider the risks posed by being exposed to multiple carcinogenic pesticides on the same food or in the complete diet.

Ultimately, as in the case of CFCs, methyl bromide, and other ozone depleters, there should be a phase out of food tolerances for carcinogenic pesticides over the next five to seven years. Those carcinogenic food use pesticides whose tolerances can most readily be phased out should be revoked first, based upon a schedule established by EPA considering the availability of alternatives. Upon a finding by EPA that there are safer alternative methods of pest management that would not lead to a carcinogenic food residue, EPA should be required to revoke the tolerance for that carcinogenic pesticide residue. No new tolerances for pesticides that are carcinogens could be issued.

Tolerances for pesticides now categorized as A, B, and "possible" human carcinogens whose risks EPA has determined are quantifiable ("Cq") would be phased out no later than 7 years from the date of enactment. Any tolerance for a pesticide which EPA has already determined is a possible human carcinogen but whose risks are not quantifiable ("unquantifiable C") would be covered by the phaseout on the same date as a Cq pesticide unless the registrant demonstrated to EPA's satisfaction that its chemical is probably not a carcinogen. Food tolerances for existing pesticides determined to be A, B, or C carcinogens for the first time after the date of enactment would be phased out within 7 years from such determination. These phase outs would result in the revocation of the carcinogenic pesticide's tolerance by operation of law without further EPA action at the end of the "sunset" period. The law would provide a clear process for one-stop EPA determinations of the category of the pesticide. Pending the ultimate phase-out, progress would have to be made towards implementing alternatives and eliminating the carcinogenic pesticide's tolerance.

In tandem with this phase-out of carcinogenic pesticide tolerances, EPA and USDA would be required to adopt an aggressive national program of research, development, and local demonstration to identify and assure the availability of alternatives to the pesticides subject to the tolerance phase out (see section III.A. below).

B. Kennedy-Waxman Reforms as a Legislative Vehicle.

Senator Ted Kennedy and Congressman Henry Waxman have introduced companion House and Senate bills that would serve as a good vehicle for food safety reform. The bill amends the Federal Food, Drug and Cosmetic Act (FFDCA) to better control pesticide residues in foods. It would establish a maximum calculated lifetime dietary risk of one cancer in a million people exposed to food residues of each pesticide, is intended to protect the public from other health effects from dietary pesticide residues, and would require special protections for children. It establishes a strictly health-based standard for pesticide residues, does not allow the consideration of the "benefits" of a pesticide to override health problems, and covers all pesticide ingredients. However, the bill needs to include a phase-out of carcinogenic food residues and three other amendments to make it consistent with the reforms noted below before we can support it.

1. **Standard for Protection of Children.**

Children are particularly vulnerable to pesticides. As critical systems in the body develop, even low doses of certain pesticides may cause dysfunction of the nervous, immune, endocrine, reproductive, and other systems as well as cancer. New evidence shows potentially severe impacts on developing fetuses whose mothers are exposed during pregnancy via food, air, or water.

It is widely expected that the National Academy of Sciences' long-awaited report on the risks posed to children from pesticides residues in foods will conclude that current EPA

policy inadequately protects children. There are provisions in the Kennedy-Waxman bill intended to protect children, but amendments to the bill will be needed to correct the deficiencies in EPA policies identified by NAS. Amendments should also require the development of methods to assess risks of maternal transfer to offspring from non-cancer health effects and the setting of tolerances that prevent these effects.

2. Labeling of Foods Containing Carcinogens.

Consumers express strong support for labeling of foods to inform them of pesticides used on their foods. For example, a March, 1993 poll commissioned by Public Voice for Food and Health Policy found that 86 percent of the public "strongly agreed" that Americans have a right to know about the chemicals used on the foods they buy in their supermarket; 79 percent said they "strongly favor tough laws requiring clear labeling of the chemicals and pesticides used to grow a food product." Thus, we recommend that at a minimum, until a pesticide that EPA has determined is a possible or worse carcinogen is phased out, the food should be labeled to inform consumers of the potential health effects of the chemicals used on their foods.

3. Non-Cancer Health Effects.

Although the Kennedy-Waxman legislation is intended to assure that there is a "reasonable certainty of no harm" from eating allowable residues on foods, the bill's provisions regarding health effects other than cancer need clarification. It should be made unambiguous in the bill or its legislative history that there will be mandatory protection of the public from non-cancer health effects such as impacts on the endocrine, nervous, and reproductive systems.

III. FIFRA Reform.

In addition to the amendments to the Federal Food, Drug and Cosmetic Act recommended above to reduce the risks posed by pesticide residues on foods, we believe that it is critical that broader pesticide reforms be adopted to reduce the risks pesticides pose to farmers, farm workers, surface, ground, and drinking water, fish, wildlife, and the environment, and the public generally. Such reforms should take the form of a package amendments to the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). The reforms we urge that likely require legislative changes in FIFRA include:

A. Accelerating Alternatives.

Agricultural pesticide use has continued to increase despite growing public concern and farmers' desire to cut production expenses. The lack of alternatives to hazardous pesticides has prevented the use of safer more environmentally benign pest control methods

in U.S. agriculture. It also has discouraged EPA from removing hazardous pesticides from the marketplace.

1. **Phasing Out and Encouraging Targeted Research and Development on Alternatives to High Risk Pesticides (Sun Set/Sun Rise).**

FIFRA should be amended to require the establishment of a process to phase out the highest risk pesticides and to replace them with safer alternatives--a "sunset-sunrise" provision. Statutory criteria should define those high risks of concern, including pesticides causing numerous farm worker or other poisonings, and pesticides with especially severe health or environmental risks such as cancer, reproductive and developmental abnormalities, and environmental persistence or bioaccumulation. Those pesticides should then be required to be phased out over a reasonable time period, with interim use reduction requirements. Targeted research and development on alternatives to those pesticides, on a crop cluster basis, should be required in an effort to identify and demonstrate biological or other safer pest management techniques.

The over-arching goal of these reforms should be reduced reliance on pesticides generally, and reduced use of the riskiest pesticides in particular, to protect the integrity of the environment. EPA would still be required to cancel or suspend any pesticide irrespective of any phase-out period, if the agency makes the applicable statutory FIFRA finding regarding a pesticide's unreasonable adverse effects.

2. **"Minor" Use Pesticides.**

A small market for chemical or non-chemical products, whether new or old registrations, has limited economic return. Many registrants therefore are unwilling to invest money in narrow-spectrum, host-specific products. Yet most of these are the new generation of chemicals and biologically-based products that are far safer in terms of public health and environmental effects, and provide more enduring control of the target pest. We support substantial increases in IR-4 to develop alternatives to conventional pesticides for minor and major crops.

Growers say that pesticide registrants have been voluntarily cancelling the uses of some pesticides on so-called "minor" crops--a category that includes all fruits and vegetables, and most other crops except the handful of "major" crops such as wheat, corn, and soybeans. According to these growers, these registrations have been sacrificed because the pesticide registrants will not recoup the costs of collecting the data necessary to re-register the pesticide for those "minor" uses.

We oppose sweeping "minor use" legislation proposed by the "Minor Crop Alliance" as it would bring little long-term benefit to growers and would only add to the inefficiencies that burden EPA's scarce resources. We also oppose any effort to waive or delay the core health, safety and environmental data requirements for minor use pesticides.

However, we support imposing fees on growers to pay for additional residue testing required for registration. Where growers can demonstrate that an effective pesticide they seek to keep on the market will be withdrawn for economic reasons, and there is no evidence of farm worker, health, or environmental problems caused by the chemical, they would be eligible to seek incentives and funding pending final action on the pesticide.

3. Expediting Registration of Safer, New Generation Pesticides.

Sound alternatives to conventional pest controls are needed by growers who face more pressure from pests because of resistance to certain available pesticides, introduction of exotic pests, or concerns about safety of compounds currently in use. Applications for registration of pesticides which are derived from naturally occurring substances, are biologically based, or are genetically engineered, should be evaluated appropriately to reflect their biological or chemical uniqueness. Many new generation pesticides are used differently from conventional pesticides and potentially affect the environment in different ways.

Thus, one goal of FIFRA reform is to replace high risk pesticides, and to conserve and enhance populations of effective natural biological control agents to the greatest extent possible. EPA should accelerate the evaluation process for registration of new generation pesticides--products that are essentially non-toxic, unlikely to be used extensively, and are very selective. Congress should build upon the incentives contained in the New Generation section of H.R. 3742.

4. Record Keeping and Reporting.

In order for EPA and states to adequately understand and regulate pesticide applications, set tolerances, track pesticide use patterns, and establish priorities in the pesticide program, reliable data on actual pesticide use must be collected. The regulators and the public have a need for this information to fully carry out pesticide reforms. FIFRA should be amended to require pesticide use data to be recorded by all applicators of pesticides, and reported to state and/or federal officials. Information on the use of pesticides also should be immediately available to health care workers in the event of emergencies such as possible pesticide poisoning.

B. Humanizing FIFRA.

FIFRA should also be reformed to better reflect the very real human impacts of pesticide use, and to be more responsive to those most affected by pesticides' adverse effects--for example, the farm workers and those affected by pesticide violations. Similarly, FIFRA must consider the impacts on people abroad of using risky pesticides exported from the U.S., and the impacts of these exported pesticides on people in the U.S. exposed when the pesticides come back on foods. Below, we propose certain reforms intended to help achieve this goal.

1. Farm Worker Protection.

Farm workers who plant, grow, and harvest our foods, particularly fruits, vegetables, and certain other labor-intensive crops, are often put at the greatest risk from pesticide exposure. However, to date the protections of farm workers under current law have been woefully inadequate, causing what has been estimated, according to the General Accounting Office, to be 300,000 pesticide poisonings each year. These farm workers deserve protection like workers in all other occupations from chemical hazards in the work place, under the Occupational Safety and Health Act. We urge the amendment of FIFRA to clarify that OSHA has jurisdiction to protect farm workers in the same way it can protect all other workers.

2. Whistle Blower Protection.

Many environmental laws other than FIFRA protect "whistle blowers"--workers who report possible violations of the law--from employer retaliation. Workers who make or use pesticides, and those who otherwise may have information about hidden violations of FIFRA, should also be protected from retaliation if they report possible violations to state or federal officials. We urge that a whistle blower protection amendment be added to FIFRA, modeled upon the whistle blower protection provision enacted last year in the Energy bill.

3. Citizen Suit Provision.

A citizen suit provision like that recently adopted in the Clean Air Act and embodied in every other major environmental law, should be added to FIFRA. As with other citizen suit provisions, the FIFRA provision should authorize citizens to sue federal agencies for failure to perform non-discretionary duties under the Act, and to sue violators of the Act for their violations. The penalties assessed against violators should go to the Treasury or to other judicially-approved purposes to benefit the environment in the area affected or potentially affected by the violation.

4. Restrict Export of Banned and Unregistered Pesticides to End the "Circle of Poison."

When pesticides that have been banned, severely restricted, or not registered in the U.S. are exported from the U.S. to other countries--particularly less developed countries--they can cause severe health and environmental problems in the nation to which they are exported. These pesticides may end up on American dinner tables as food residues on imported foods. Every year, we eat more foods contaminated with chemicals that U.S. growers cannot use. This problem has been labeled the "Circle of Poison."

We urge the adoption of strong Circle of Poison legislation modeled on the original 1989 bill introduced by Congressmen Synar, Glickman, and then-Congressman Panetta, and in the Senate by Senator Leahy and then-Senator Gore. This legislation would prohibit the export of banned or unregistered pesticides from the United States into other nations, and require prior informed consent of the receiving nation before highly toxic pesticides are exported with clarified worker protection provisions.

C. Getting the Bugs Out of FIFRA.

In addition to the substantive reforms proposed above, FIFRA must be modernized to streamline and strengthen many of its antiquated, inefficient, and cumbersome procedures and enforcement provisions.

1. Streamlined Cancellation Procedures.

EPA officials and other experts, including former EPA Administrator William Reilly, have often complained that once EPA determines that a pesticide causes unreasonable adverse effects, under FIFRA's inordinately complex and labyrinthine procedures, it takes four to eight or even ten years for EPA to cancel the pesticide. Even the Bush Administration stated that there is an urgent need to simplify the cancellation process and proposed legislation to take a modest step towards that goal.

The most important changes needed in FIFRA's cancellation provisions are eliminating the administrative adjudicatory hearing, reducing the redundant multiple layers of review within EPA, and streamlining the review in the Courts of EPA's actions. A streamlined informal rulemaking process, an informal administrative hearing with a time limit, and simplified and expedited internal and judicial review (by the Court of Appeals rather than time-consuming and repetitive de novo district court review), would fully meet all due process requirements, and is urgently needed. The Bush Administration reform bill, and a pesticide reform bill as introduced by Rep. Charlie Rose last Congress, H.R. 3742, included reforms in the cancellation procedures that are an important starting point in achieving this streamlining goal. We urge the adoption of the original (pre-markup) Rose bill's cancellation reform provisions, although a few modest improvements in those provisions are needed to assure efficient and effective EPA action.

2. Streamlined Suspension Procedures.

EPA also should be given the authority to expeditiously suspend a pesticide posing imminent risks, without being required to first complete a detailed benefits assessment. A registrant or other person should be authorized to petition EPA to consider additional information, but the suspension should stand until EPA or a court reverses EPA's position, or until the suspension expires and EPA has not yet completed a cancellation proceeding.

Judicial review should be in the appeals court. Most of these reforms were proposed in the Bush Administration bill and in last Congress' Rose bill, H.R. 3742, as introduced. We urge the adoption of the Rose bill's suspension provisions as introduced, although the bill should be clarified in a few respects to assure that EPA can take swift and unimpeded action to protect the public or environment in emergency situations.

3. Penalties and Enforcement.

FIFRA's enforcement provisions should be substantially streamlined and updated. The Bush Administration recognized the need for beefed-up and simplified state and EPA enforcement provisions, and proposed legislation that would have taken a small step in that direction. Congressman Charlie Rose's bill last Congress also included some enforcement reforms.

FIFRA's enforcement provisions should be improved by building upon the Bush and Rose bill's provisions, clarifying EPA responsibility and authority to enter, inspect, and take samples at all locations where violations may have occurred, to issue subpoenas, to directly impose administrative penalties and to collect or seek imposition of increased civil and criminal penalties. It also should be clarified that states enjoy such enforcement authority in federal court, and that states with primary enforcement responsibility must have the authority to impose administrative civil penalties.

4. Higher Registration and Re-Registration Fees.

EPA has admitted that it will miss the 1997 deadline for re-registration of all old pesticides imposed in the 1988 FIFRA Amendments, due in large part to a shortfall of tens of millions of dollars in EPA resources. In addition, there simply are insufficient resources available for EPA to register new pesticides and to otherwise implement the pesticide program. This shortfall should be made up through the imposition of increased fees on pesticide registrants for re-registration and continued registration of their chemicals.

IV. Conclusion.

Together, these proposed changes would make our food safer, and help to protect workers and the environment from the dangers posed by pesticides. Moreover, our proposals would begin the process of shifting towards safer pest management practices while insuring a wholesome and plentiful food supply.



ENVIRONMENTAL WORKING GROUP™

Testimony Before the
Subcommittee on Department Operations and Nutrition

House Committee on Agriculture

Prepared by

Richard Wiles
Director, Agricultural Pollution Prevention Project
Environmental Working Group

August 2, 1993

Mr. Chairman, distinguished members of the Subcommittee. Thank you for the opportunity to testify today on HR 1627, the *Food Quality Protection Act of 1993*.

I am Richard Wiles, director of the agricultural pollution prevention project at the Environmental Working Group, a nonprofit environmental research organization here in Washington, DC.

On June 28, 1993, the Environmental Working Group released the report *Pesticides in Children's Food*. This study presented the results of original analyses on the presence and risks from pesticides in the food supply.

We documented for the first time the prevalence of multiple residues in single foods, and showed that it is not uncommon for children to eat single pieces of fruits or vegetables with 5 or more pesticides on them. The EPA regulates pesticides, meanwhile, as though people are exposed to them one at a time. We illustrated the severity and imbalance of pesticide exposure early in life, showing that up to 35 percent of lifetime exposure to some carcinogenic pesticides occurs by age 5. We then estimated the risk presented by this disproportionately heavy early exposure to eight carcinogenic pesticides routinely found in just 20 fruits and vegetables. The result is that for the average child, the EPA's "acceptable" lifetime level of risk is exceeded by age one.

The concurrent report from the National Academy of Sciences, *Pesticides in the Diets of Infants and Children*, recommended basic changes in the current regulatory system to adequately protect young children from pesticides.

HR 1627 does not implement the NAS committee's recommendations and does not guarantee protection for children. We therefore strongly oppose its enactment.

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Instead, we support HR 872, *The Pesticide Food Safety Act of 1993*, introduced by Mr. Waxman, with strengthening amendments. HR 872, and its companion bill, S. 331, introduced by Mr. Kennedy in the Senate, provides special protection for children, establishes a strict health based standard for pesticide residues in food, and implements many of the key recommendations of the National Academy of Sciences Committee. A comparison of the way the Waxman/Kennedy bills and the Lehman, Bliley, Rowland bill address the key recommendations of the NAS committee report is attached.

In its consensus report, National Academy of Sciences committee on pesticides in the diets of infants and children found the entire pesticide tolerance and regulatory system lacking, and particularly inadequate in protecting young children. The Academy concluded that "tolerances are not based primarily on health considerations" and that "the current regulatory system does not specifically consider infants and children." To address these failings, the committee recommended "that EPA modify its decision making process for setting tolerances so that it is based more on health considerations than on agricultural practices," and that specific changes be made to protect young children.

The committee made clear that children need special protection from pesticide residues in food. Specifically, the committee recommended that "in the absence of data to the contrary, there should be a presumption of greater toxicity to infants and children." To account for this likely increased sensitivity the committee urged that "the 10-fold factor traditionally used by EPA and FDA for fetal developmental toxicity should also be considered when there is evidence of postnatal developmental toxicity and when data from toxicity testing relative to children are incomplete." In addition, the committee cited the common occurrence of simultaneous exposures to different pesticides with the same toxic effect, and recommended accounting for multiple exposure in regulatory risk assessments.

Finally, the committee left no doubt about the basic goal of pesticide regulation as it relates to food residues: "Children should be able to eat a healthful diet containing legal residues without encroaching on safety margins. This goal should be kept clear."

Recognizing the seriousness of the issue and the failure of current policies, the Clinton Administration, in an historic announcement, proclaimed a new pesticide policy based on use-reduction and the promotion of sustainable agricultural practices. This policy was made possible by the welcomed and unprecedented cooperation between the USDA, FDA, and the EPA. We are pleased that the Administration will look to our report, *Pesticides in Children's Food*, and the report from the National Academy of Sciences, *Pesticides in the Diets*

of *Infants and Children*, in implementing this policy. To quote from the Administration's announcement:

We expect to use the upcoming reports from the National Academy of Sciences and the Environmental Working Group on children and pesticides as a basis for formulating the legislative and regulatory policies needed to put the Administration principles into effect.

HR 1627 is completely unresponsive to the Administration's new goals.

The current pesticide regulatory system is built on the notion of maximum acceptable risk. The goal is not to produce abundant and affordable food using the least amount of pesticides possible; rather it is to set and allow maximum acceptable levels of human and environmental exposure to hundreds of pesticides in thousands of formulated pesticide products applied to hundreds of food and feed crops. The foundation of this paradigm is the untenable notion that scientists and regulators can accurately assess the risks from residues of 20,000 different formulated pesticide products all interacting in the environment and the human body.

Not only is the basis of this process highly implausible, it is extremely expensive. It provides no incentives for agricultural production innovation, and allows maximum opportunities for delay. It is extremely bureaucratic, unpredictable, founded on misplaced burdens of proof, and divorced from market forces. It captures all of the bad elements of failed regulatory policies in other areas. It can be rightly characterized as "end of the pipe" regulation for food.

HR 1627 enshrines into law all of the bad features of current policies.

Beyond these general flaws, we oppose HR 1627, the Lehman, Bliley, Rowland Bill, for many specific reasons. Some of the most important are as follows:

HR 1627 is bad for children.

- It does not require specific protection for children.
- It does not ensure that exposure to pesticides at legal limits is safe for children.
- In fact, HR 1627 does not implement a single finding of the NAS Committee report; it does not require an assessment of exposure from all sources, as recommended by the Academy panel, nor does it include any special methodologies or safety factors to protect children, as recommended by the NAS panel.

HR 1627 is bad for the public health.

- HR 1627 repeals the Delaney Clause of the Federal Food Drug and Cosmetic Act, the most protective, albeit imperfect, preventative public health standard in federal law. It is replaced with the weak, ineffective, and entirely subjective risk benefit standard currently contained in the Federal Insecticide Fungicide and Rodenticide Act.
- HR 1627 codifies in law the current regulatory bias toward agricultural benefits, and fails to acknowledge the need for greater protection of the public health, as recommended by the NAS committee report. HR 1627 specifically allows economic benefits to farmers to justify public health risks in excess of the level determined as negligible by the EPA.

HR 1627 does nothing to reduce the use of pesticides.

- On June 25, 1993, the Clinton Administration announced an historic shift in pesticide policy, declaring a commitment to pesticide use reduction and the promotion of sustainable agriculture. HR 1627 does nothing to advance this goal.

HR 1627 weakens currently inadequate standards for food tolerances.

- The EPA currently establishes food tolerances by adding up the risks presented by all food uses of a pesticide. HR 1627 appears to weaken this standard by requiring that exposure calculations are reduced to a single pesticide on a single food. HR 1627 further does not respond to the recommendations of the NAS committee to include all routes of exposure (food, water, garden, and home applications) in the establishment of food tolerances.

All food production and pesticide regulatory policies should work coherently toward the same goal: producing food with the least amount of pesticides possible, and where appropriate and reasonable, no pesticides at all. This goal should be accomplished at the least cost to taxpayers, consumers, and farmers.

Within this framework, certain specific policy changes must be made.

- Pesticides that pose unacceptable risks to children and other high risk populations must be phased out.
- Pesticides that remain on the market must meet strict health-based criteria designed specifically to protect children and other sensitive or highly exposed groups.

- USDA must embark on an initiative to provide pest control alternatives to growers of crops most dependent on pesticides that present the greatest risks to human health and the environment.
- Consistent and enforceable market incentives that reward growers for reduced and low pesticide use must be established.

HR 1627 accomplishes none of these goals, and erects significant obstacles to their achievement. We therefore, strongly oppose its enactment.

(Attachment follows:)

Protecting Children from Pesticides in Food
Meeting the Standards of the National Academy of Sciences
A Comparison of the Waxman/Kennedy and Lehman, Bliley Bills

Issue	National Academy of Sciences	Waxman HR 872 Kennedy S 331	Lehman/Bliley HR 1627
Special protection for children	Children need special protection that the current system does not provide. The pesticide tolerance setting system should be changed so that children are explicitly protected.	Provides explicit protection for children, with an emphasis on young children and infants under age 5.	No guarantee of protection for children. Consideration of the needs of children is allowed, but not required.
Risk Standard	Recommends a 10 fold safety factor when data relative to children are incomplete. Recommends development of new cancer risk assessment methods to better understand the potential increased risk to young children.	All legal exposures must pass the reasonable certainty of no harm test. Requires special protection from carcinogens for children under age 5, ensures an ample margin of safety from non-cancer causing pesticides.	Provides the EPA with the same flexibility allowed under current law. Proposes a negligible risk standard with no required special health protection for children.
The role of agricultural benefits	"To ensure that infants and children are not exposed to unsafe levels of pesticide...tolerances should be based more on health considerations than agricultural practices."	Adopts a strict health based standard. Agricultural benefits not allowed to compromise public health protection.	Allows agricultural benefits to override protection of the public health in certain situations.
Protection from non-food exposures to pesticides	Exposure from all sources should be included when determining safe levels of pesticides in food.	Requires the inclusion of all dietary sources of exposure, including water, in setting food tolerances.	No requirement that other exposure be considered. Appears to weaken the current standard by requiring exposure calculations to be reduced to a single pesticide on a single food.
Protection from exposures to multiple pesticides with a common toxic effect	Exposures to pesticides that cause similar health effects should be considered.	Requires consideration of multiple exposures to non carcinogenic pesticides that cause similar effects.	Does not require consideration of exposure to multiple pesticides with a common toxic effect.
Safety of exposure to pesticides at the legal limits (tolerances) - restoring the integrity of the tolerance system	Exposure to pesticides in food at the legal maximum levels (tolerances) should be safe for children.	Exposure to pesticides in food at the legal limit (the tolerance) should be safe for children. Tolerances should be adjusted to reflect actual residues.	No explicit provision requiring that the legal limit reflect safe and actual exposures.



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TESTIMONY OF ERIK D. OLSON
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NATURAL RESOURCES DEFENSE COUNCIL

BEFORE THE
DEPARTMENT OPERATIONS AND NUTRITION
OF THE
HOUSE COMMITTEE ON AGRICULTURE

HEARINGS ON H.R. 1627:
LEGISLATION TO
AMEND PESTICIDE REGULATION UNDER
THE FEDERAL INSECTICIDE,
FUNGICIDE, AND RODENTICIDE ACT
AND THE FEDERAL FOOD, DRUG, AND
COSMETIC ACT

AUGUST 2, 1993

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I. INTRODUCTION AND OVERVIEW.

Chairman Stenholm and distinguished members of this Subcommittee, I am Erik D. Olson, Senior Attorney with the Natural Resources Defense Council (NRDC), a national non-profit public interest organization dedicated to protecting public health and the environment, with over 170,000 members nationwide. We appreciate this opportunity to testify today regarding H.R. 1627, legislation amending the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and Federal Food, Drug, and Cosmetic Act (FFDCA).

As we testified before this Subcommittee on June 8, 1993, we believe that FIFRA has been a failure. It has failed to assure farmers and the public an orderly, predictable, and timely review of pesticides and to encourage the development of alternatives to problem pesticides. It has not protected farm workers from poisoning. It has been unable to assure public confidence that the government has prohibited contamination of foods and drinking water with pesticides. It has not prevented environmental problems ranging from pesticide contamination of lakes, rivers and streams, to wildlife poisonings and reproductive failures, to fish contamination with pesticide residues.

Unfortunately, the federal government--USDA and EPA in particular--has failed to provide farmers with the tools they need to predict what will be available next year, and to make the transition to reduced reliance on toxic and environmentally dangerous pest control methods.

Moreover, FIFRA and the FFDCA have failed to redress the need for assuring a safe food supply. Cancer and other risks of pesticide residues on food have been largely unaddressed for decades.

A coalition of public health, labor, consumer, and environmental organizations recently released our Pesticide Reform Agenda , which lays out our views on food safety and pesticide reform measures that need to be taken. We have supplied the Subcommittee with copies of this reform agenda, which calls for comprehensive measures to reform the FFDCA and FIFRA. However, we have been asked to testify on our views on H.R. 1627, the so-called Lehman-Bliley "Food Quality and Safety Act of 1993," not on our reform agenda.

We appreciate that the sponsors of the Lehman-Bliley bill introduced this legislation recognizing the need for reform, in a good faith effort to improve pesticide regulation. While we are aware that many members of this Subcommittee are cosponsors of the Lehman-Bliley bill, we regrettably must vigorously oppose the bill, because it is our belief that it would undercut even the weak current protections of the food supply from pesticide contamination.

The Lehman-Bliley bill also would fail to assure a remedy for certain of the problems posed for infants and children by pesticides in foods, recently recognized by the National Academy of Sciences (NAS) in the important recent study entitled Pesticides in the Diets of Infants and Children. We are strong

supporters of science-based decisions, and we believe that scientific uncertainty, which will always exist, cannot be an excuse for regulatory paralysis. We also believe that many of the proposals and issues raised by the Academy are inadequately addressed, or are actually directly contradicted, by certain provisions of the Lehman-Bliley bill.

The Kennedy-Waxman Food Safety Legislation (H.R. 872), while requiring certain amendments to strengthen it (such as a phase-out of carcinogenic pesticide residues, a requirement for labeling of foods treated with carcinogenic pesticides, and certain additional assurances that non-cancer health effects are dealt with sufficiently), is far more responsive to the NAS report and is a far better vehicle for food safety reform than the Lehman-Bliley Bill.

II. THE LEHMAN-BLILEY BILL FAILS TO MEET THE NEED FOR STRONGER FOOD SAFETY REGULATIONS.

The Lehman-Bliley bill's provisions revising the Federal Food, Drug, and Cosmetic Act's (FFDCA) pesticide residue-related provisions are fundamentally flawed. The bill would give EPA the discretion--and in some areas even would require the agency--to provide less protection of public health than is provided under current law. Thus, if the choice were between the Bliley-Lehman bill or current law, we believe that current law is clearly preferable.

The Lehman-Bliley bill also fails to require EPA to redress many of the agency's failures identified by NAS in the pesticide

residue regulation area. The bill actually chisels into statutory stone many of the problems that NAS noted were of most serious concern in the protection of health. The most important problems with the bill's FFDCA provisions are discussed below.

A. Locking into Statute the Override of Health Considerations By Agricultural Benefits.

1. The National Academy of Sciences Criticized the Override of Health Considerations by "Benefits" Considerations.

The Lehman-Bliley bill enshrines into law the notion that even if a pesticide residue poses a significant risk to the public, including children and infants, the residue will still be allowed and "deemed to be adequate to protect public health" if use of the pesticide yields various purported benefits.

It was precisely this kind of loose, often benefits-driven approach that got the nation's pesticide program into the untenable situation that the National Academy of Sciences was critical of in its report on the risks posed by pesticides to children. For example, the NAS committee, while saying that the "requirements of agricultural production" should be considered, was critical of EPA's over-reliance on benefits arguments, noting that under current practice, tolerances

are not based primarily on health considerations....To ensure that infants and children are not exposed to unsafe levels of pesticide residues, the committee recommends that EPA modify its decision-making process for setting tolerances so that it is based more on health considerations than on agricultural practices....[H]uman health considerations would be more fully reflected in tolerance levels. Children should be able to eat a healthful diet

containing legal residues without encroaching on safety margins. This goal should be kept clear.¹

Thus, it is clear that the NAS' view is that if a pesticide residue "encroach[es] on safety margins" for kids, it should not be allowed. The Lehman-Bliley bill fails on this critical test, by providing that benefits may override health considerations.

2. The Lehman-Bliley Bill's Benefits Override of Health Considerations is Extremely Broad.

The Lehman-Bliley Bill's benefits test is so broad that virtually any pesticide residue, no matter how risky, could be argued to be legal. For example, the pesticide residue remains legal even if it presents a significant risk (apparently including an acute poisoning risk), if the chemical company making the pesticide successfully argues that "the unavailability of the pesticide would limit the availability to consumers of an adequate, wholesome, and economical food supply, taking into account regional and domestic effects, and such adverse effects are likely to outweigh the risk posed by the pesticide residue."

This benefits test is so broad and fraught with litigation possibilities that it might be called the "Pesticide Lawyer's Full Employment Opportunity Act." Under this test alone, we believe that practically any pesticide residue arguably could be legal, and that at a minimum litigation over its meaning could keep dangerous pesticide residues on foods for years while EPA and the courts sort out its meaning.

¹NAS, NRC, Pesticides in the Diets of Infants and Children, at 8-9 (emphasis added) (1993)

For example, let us assume that a hypothetical fungicide is a carcinogen and also carries an acute poisoning risk if found on foods in high doses. EPA decides to reduce its allowable residues on strawberries and blueberries and to ban its use altogether on carrots and kumquats because of the large risk it poses to infants and children. However, the industry argues that reducing these allowable residues would make it difficult to grow and distribute these crops from a few pockets of two states, and could, if certain assumptions are made, actually increase the prices of these foods by a couple of percent, so it takes EPA to court.

The fact that these pesticide residues pose large health risks to children, that the potentially affected farmers could grow other crops, that normal weather-related and other market fluctuations in the price of the crops dwarfs pesticide availability as a source of price fluctuations, and that farmers elsewhere can make up the difference, is irrelevant, the industry lawyers would argue, because the new rule will adversely affect the availability of carrots and kumquats and could increase the price of the fruits by a couple of percent in a few local regions for a couple of months. The industry lawyers would also argue that under the law, the consumer might pay a couple of percent more for the fruits and carrots in some months and this would therefore reduce the "availability to consumers of an adequate, wholesome, and economical food supply, taking into account regional and domestic effects...." If EPA disagreed, the issue

would go through multiple levels of EPA review, and finally through potentially two levels of court challenges. As many as ten years or more later, the courts may resolve the issue, after children have been exposed to these risks for a decade.

This unacceptable scenario is precisely the nightmare that we foresee with the Lehman-Bliley bill, and one reason that we oppose it vigorously. The Kennedy-Waxman bill, on the other hand, would take a major stride towards reducing the availability of these arguments and establishing a health-based standard.

B. The Lehman-Bliley Bill Fails to Define "Negligible Risk" Clearly, Opening the Door to Retention of the Status Quo--Or Worse.

The Lehman-Bliley bill allows an essentially undefined level of "negligible risk" from pesticide residues. There is no quantitative or other clear definition of what is "negligible," so if EPA were to decide that a one in one hundred cancer risk is "negligible," that arguably may be found legal, particularly given the lenient review of agency decisions provided by the courts. The most likely scenario under the bill, however, is that EPA will say that a certain level of risk is negligible (e.g. a one in ten thousand cancer risk for the "average" consumer, a much larger risk for kids) and will eventually take regulatory action based on that definition. The pesticide industry will then sue EPA for its actions arguing that the risk is "negligible" and that the benefits of the pesticide outweigh its risks.

Under the bill, industry could tie up the agency in court for years, keeping their pesticides on the market because "negligible" is essentially undefined and benefits are so broadly defined. The Kennedy-Waxman bill, on the other hand, specifically states that no risk for a non-threshold health effect of over one in one million to the most sensitive sub-population is allowed, and that acute effects of pesticides must be avoided with a margin of safety.

C. The Lehman-Bliley Bill Fails Specifically to Require EPA to Protect Infants and Children.

The National Academy of Sciences' recent report found that infants and children may be at special risk from pesticides in foods due to their special sensitivity to toxins and due to their heavy consumption of certain foods. The Academy recommended that due to children's special sensitivity, EPA should add an additional 10-fold safety factor to protect infants and children "when data for toxicity testing relative to children are incomplete."² In addition, the NAS recommended that "[m]ost importantly, estimates of expected total exposure to pesticide residues should reflect the unique characteristics of the diets of infants and children..."³ The panel also found that "[a]ge-related differences in exposure patterns [are] most accurately

²NAS, NRC, Pesticides in the Diets of Infants and Children, at 9.

³Id. at 7.

illustrated by using 1-year age grouping of data on children's food consumption."⁴

While the Lehman-Bliley bill provides that EPA is to consider dietary exposure levels and sensitivity of sub-populations "among other relevant factors," there is no specific requirement that EPA's final decision protect the infants and children from the special effects of pesticides on infants and children, nor is there a specific mandate that EPA adopt any special safety factor to protect them. EPA has long argued that it "considers" infants and children--yet the record indicates that often the actual tolerances simply fail to sufficiently protect them. The Lehman-Bliley bill simply would not require EPA to change this longstanding practice. Moreover, as noted earlier, the bill fails to define what risks are "negligible" and allows supposed benefits of the pesticide to override its health effects--so even if EPA "considers" these effects on infants and children, the final decision may not be very protective of them.

The Kennedy-Waxman bill, on the other hand, does specifically require that EPA establish a standard that is based on infants and children's exposure on a yearly age bracket basis, as NAS suggested. The Kennedy-Waxman bill also mandates that EPA's final decisions be protective of infants and children considering their special sensitivity.

⁴Id. at 6.

- D. The Lehman-Bliley Bill Apparently Requires EPA to Look at One Residue at a Time, Failing to Mandate that EPA Consider Exposure to Residues of the Same Pesticide on Multiple Foods.

The Lehman-Bliley bill as drafted apparently provides that each pesticide residue's risks are to be calculated on an extremely narrow basis. Thus, under the bill's approach, a pesticide applied to scores of crops could be used on each of those crops at a "negligible" risk level, posing total risks many times higher than the "one in ten thousand" or other "negligible" risk level for all crops to which the pesticide is applied. This directly contradicts the recommendation of the NAS that "[t]o determine total dietary exposure to a particular pesticide, intakes from all foods on which residues might be present need to be combined."⁵ The Kennedy-Waxman bill requires EPA to establish the tolerance after considering exposure to all foods upon which the residue is found, as NAS recommends.

- E. The Lehman-Bliley Bill Fails to Require that Exposure to Pesticides from Drinking Water and other Non-Dietary Sources of Exposure be Considered.

The Lehman-Bliley bill apparently requires the establishment of tolerances based exclusively upon consideration of dietary exposure to the pesticide from the single food at issue. It apparently does not require EPA to look at exposure to the pesticide via drinking water or via other routes such as air. This again directly contradicts the recommendations of the NAS

⁵Id. at 318 (emphasis added).

that "[m]ost importantly, estimates of total exposure to pesticide residues should...account also for all non-dietary intake of pesticides."⁶ The Academy recommended that in estimating dietary intake of pesticides, "water intake and food intake should both receive full consideration,"⁷ and "[n]on-dietary exposure including air, dirt, surfaces, lawn, and pets should also be considered."⁸ Again, it appears, the Lehman-Bliley bill misses the mark, failing to mandate that EPA change the way it does business in establishing tolerances. The Kennedy-Waxman bill requires EPA to look at drinking water exposures, but apparently does not require EPA to consider non-dietary exposures.

F. The Lehman-Bliley Bill Fails to Require that EPA Consider the Effects of Multiple Pesticides With a Common Toxic Effect.

The Lehman-Bliley bill provides that EPA is to set tolerances for a single pesticide food residue on a single food. There is no requirement or provision for looking at exposure to multiple pesticides that have a common toxic effect--for example, neurotoxicity or carcinogenicity. Again, this fails to assure the implementation of the NAS recommendation that "[e]stimates of

⁶Id. at 7.

⁷Id. at 197 (emphasis added).

⁸Id. at 11.

total dietary exposure should be refined to consider intake of multiple pesticides with a common toxic effect."⁹

The Kennedy-Waxman bill also fails to specifically deal with this cumulative exposure problem (which may cause synergistic or additive effects, for example). The cumulative exposure issue--and the lack of data on the extent of cumulative exposure and on its interactive effects--is a key reason why we favor the ultimate phase-out of carcinogenic pesticide residues and the phase-in of safer alternatives.

G. The Lehman-Bliley Bill Requires the Consideration of "Percent of Crop Treated" Even When this Consideration is Inappropriate.

The Lehman-Bliley bill mandates that where data are available, EPA

shall calculate the dietary risk on the basis of the percent of food actually treated with the pesticide chemical and the actual residue levels of the pesticide chemical. In particular, the Administrator shall take into account aggregate pesticide use and residue data collected by the Department of Agriculture.¹⁰

The NAS committee, on the other hand, came out on the other side of this issue, stating that the scientific basis for such a percent of crop treated approach generally is lacking:

The committee does not recommend the routine application of adjustments for the percentage of crops treated in estimating dietary exposure to pesticides. Adjustments for acreage treated are appropriate only under certain conditions. For example, such adjustments may be used when there is little regional variation in acreage treated, or

⁹Id. at 11.

¹⁰Bill section 408(b)(1)(E).

when the crop is uniformly distributed at the national level.¹¹

Thus, again the Lehman-Bliley bill apparently comes out on the wrong side of the science, requiring routine application of the percent of crop treated reductions--and therefore allowing greater amounts of pesticide residues--even though the NAS states that such an approach should not generally be used.

In addition, it would appear that the Lehman-Bliley bill requires EPA to consider the percent of crop treated even when setting a tolerance for an acutely toxic pesticides. The NAS hastens to recommend against such an approach, noting that the percent of crop treated "adjustments should not be considered in the case of pesticides inducing acute toxic effects since peak exposures are of importance in this case."¹² The Kennedy-Waxman bill, on the other hand, allows percent of crop treated to be considered only in very limited circumstances.

H. The Lehman-Bliley Bill Inappropriately Prohibits States from Acting to Protect their Citizens from Dangerous Pesticide Residues Even if EPA Has Failed to Act.

The bill also would weaken current law by generally preempting states from adopting tolerances more stringent than any new EPA tolerances for pesticides. States always have had the authority to adopt such tolerances, and despite horror

¹¹NAS, NRC, Pesticides in the Diets of Infants and Children, at 318 (emphasis added).

¹²Id. at 317.

stories conjured up by pesticide industry lobbyists, only in a few well-justified cases have states used this authority.

Like the bill's local government preemption provision, this state tolerance preemption provision is unjustified and unnecessary. Not only have states only sparingly used their longstanding authority to adopt these tolerances exclusively in the most limited and necessary circumstances, but any ill-conceived state tolerance that theoretically could be adopted could be challenged in state courts as unjustified or in federal courts as an undue burden on interstate commerce under the Commerce Clause. The only exception to the ban on stricter state tolerances would be that EPA could allow a state to adopt such a tolerance if EPA finds it is "warranted by special local circumstances in the state."

III. THE LEHMAN-BLILEY BILL FAILS TO PROVIDE THE NEEDED IMPROVEMENTS IN THE PESTICIDE REGULATORY PROGRAM.

There is an urgent need to reform certain aspects of the antiquated and woefully inefficient FIFRA provisions for cancellation and suspension of dangerous pesticides. In addition, the enforcement, registration, and certain other provisions of the law also need to be updated. Moreover, while we are not unhappy with the Delaney Clause and the recent Court decision that will force EPA to finally implement that law, we are interested in broadening protection of food safety through more comprehensive food safety legislation, for which Kennedy-Waxman should serve as a vehicle.

We also urge this Committee to work with the Clinton Administration to adopt a strong FIFRA reform measure, perhaps building upon key portions of Charlie Rose's FIFRA reforms as introduced last Congress (H.R. 3742), that will remedy the problems with the Act as soon as possible. As former EPA Administrator Reilly stated, the current pesticide cancellation

process is very complicated, duplicative, and inefficient. This country cancels trading in bad stock faster than it gets rid of a bad pesticide. ... [We must] address this issue by removing one of the very duplicative parts of the process, the adjudicatory hearing that occurs after a decision has been reached by the EPA administrator on the basis of extensive scientific analysis to cancel a chemical.... Where we now have a four to eight year process from start to finish for cancellation, we ... [urge Congress to adopt reform legislation] to reduce the period to something in the range of two to three years. We have the authority to suspend a chemical under certain circumstances. But that power has only been exercised three times in EPA history. The standard for exercising it is very rigorous. The courts have in fact found that we proposed to exercise it inappropriately in the past and have prevented us from using this authority.

I got my baptism by fire on these questions ... and really found it astonishing that the statute essentially put the EPA Administrator in the position of defending a decision that concluded, first of all, that the chemical pesticide posed an unacceptable risk and was therefore a candidate for cancellation, but then, nevertheless, left us with the reality that that pesticide was going to be around for several years to come.

That really, I think, is an untenable situation. It's one that has long needed addressing. I think it's one of the strongest elements in this set of proposals [made by the Administration to reform FIFRA], that we remove the adjudicatory hearing, the de novo review that has added so many years to that process, and I would expect that anybody who looks at that will recognize that this is going to make

for a much stronger and more protective implementation of that law.¹³

Chairman Rose's bill of last year as introduced would have streamlined EPA's cancellation and suspension process, in an effort to reduce the procedural problems identified by Administrator Reilly. While a few changes to the cancellation and suspension provisions in Title I of the Rose bill as introduced are needed to assure that it will achieve its intended effect, in general we supported Mr. Rose's efforts to reform FIFRA's cumbersome cancellation and suspension procedures, and opposed weakening amendments that were attached to the bill in markup.

We also were pleased that the Rose bill provided for mandatory review of pesticide tolerances (although we believe that more frequent review than required by the bill is necessary). In addition, the bill included some needed improvements to FIFRA's enforcement and certification and training requirements, although we believe these provisions needed to go further to assure pesticides are used safely. These reforms, and certain other measures to update FIFRA, are needed to make the pesticide regulatory scheme work for America. We look forward to assisting Congress, the Administration, and other interested parties in reforming this Act.

¹³William K. Reilly, EPA Administrator, at Press Conference on the Administration's Food Proposal, October 26, 1989 (transcript by Federal News Service, Federal Information Systems Corporation, dated October 27, 1989).

A. Problems With Lehman Bill's FIFRA Reforms.

1. Preemption of Local Authority to Protect Citizens

The Bliley-Lehman bill would generally preempt state governments from regulating pesticide residues, except in extremely limited circumstances, a right that they have enjoyed since pesticides were first invented; the Supreme Court now has confirmed has recently confirmed local government authority to regulate pesticides under FIFRA. While the preemption provision theoretically allows state regulation if it is first approved by the federal government, the cumbersomeness of this procedure, and the numerous points provided for opponents to put the brakes on state rules, made it unlikely that this theoretical process allowing state rules would ever be used.

State governments should be able to continue unimpeded their sparingly-used authority to protect their citizens from pesticides. Any unreasonable state rules that theoretically may be proposed or adopted could be rejected after local debate, and if they conflict with or impede implementation of state or federal law, would be preempted under current Supremacy Clause law. Moreover, any such rule that unduly burdens interstate commerce would be prohibited by the Courts under current Commerce Clause doctrine. Thus not only is preemption of state and local authority unwise, it is unnecessary.

2. Failure to Provide for Expedited Cancellation, Suspension, Adequate Fees, and Other Needed Reforms.

In addition to the troubling preemption provision of the bill, we are concerned that the Lehman-Bliley bill does not do

enough to reduce the incentives and opportunities for endless delays in the regulatory process that have virtually shut down EPA's pesticide program. We believe there is a need for a bold overhaul of FIFRA, as proposed in our Pesticide Reform Agenda, to enable EPA to more efficiently cancel, suspend, regulate, and enforce under FIFRA, and to force EPA and USDA to help farmers find alternatives to risky pesticides.

IV. POLLUTION PREVENTION: REDUCING THE USE OF PESTICIDES

The question of chemical residues on the food we eat is a hotly debated issue. The existence of such residues is either played down by the industry as unimportant or is flatly denied. Simultaneously, there is a strong tendency to brand as fanatics or cultists all who are so perverse as to demand that there food be free of insect poisons. In all this cloud of controversy, what are the actual facts? [...]

The system by which the Food and Drug Administration establishes maximum permissible limits of contamination, called "tolerances," has obvious defects. Under the conditions prevailing that provides merely paper security and promotes a completely unjustified impression that safe limits have been established and are being adhered to. As to the safety of allowing sprinkling of poisons on our foods -- a little on this, a little on that -- many people contend, with highly persuasive reasons, that no poison is safe or desirable on food. [...] In effect, to establish tolerances is to authorize contamination of public food supplies with poisonous chemicals in order that the farmer and the processor may enjoy the benefit of cheaper production -- then to penalize the consumer by taxing him to maintain a policing agency to make certain that he shall not get a lethal dose. But to do the policing job properly would cost money beyond any legislator's courage to appropriate, given the present volume and toxicity of agricultural chemicals. So in the end, the luckless consumer pays his taxes but gets his poisons regardless. [...]

This system, however -- deliberately poisoning our food, then policing the result -- is too reminiscent of

Lewis Carroll's white knight who thought of "'a plan to die one's whiskers green, and always use so large a fan that they could not be seen.'" The ultimate answer is to use less toxic chemicals so that the public hazard from their misuse is greatly reduced. [...] In addition to making this change to less dangerous agricultural pesticides, we should diligently explore the possibilities of non-chemical methods. A great many other possibilities exist for effective insect control by methods that will leave no residues on foods. Until a large-scale conversion to these methods has been made, we shall have little relief from a situation that, by any common sense standards, is intolerable. As matters stand now, we are in little better position than the guests of the Borgias."¹⁴

For three decades since Rachel Carson wrote these stirring words, calls for essential reform of the nation's food safety laws have gone largely unheeded. When governmental agencies or private groups have demonstrated that pesticide regulation is necessary in order to protect public health, a "parade of horrors" has been conjured up by the food and agrichemical industries opposing government action. Chemical by chemical, we have been told that pesticides were "essential" to food production and that their elimination, despite clear health hazards, would wreck havoc on segments of American agriculture. Chemical by chemical, after excruciatingly long bureaucratic delays and public debate, these claims were proven false. In the early years, these apocalyptic predictions were made for the chlorinated hydrocarbons (e.g., DDT, aldrin and dieldrin). After years of litigation, these substances were finally removed from the marketplace with no noticeable impact on agricultural yields

¹⁴. Rachel Carson, Silent Spring, 1962, pp.182-184.

or production. During the Nixon and Carter Administrations, it was DBCP that stirred the greatest controversy. DBCP is a human carcinogen and potent reproductive toxin. DBCP users and manufacturers claimed that removal of DBCP from the market would have a devastating impact on the production of citrus and other commodities. After a decade of controversy, the pesticide was finally banned, first by California and then by EPA. Citrus yields increased. But Americans continue to be exposed to DBCP, which has now contaminated some 2,000 drinking water wells in California alone. A lawsuit brought by the city of Fresno is now pending against DBCP's producers for several hundred million dollars in damages resulting from DBCP pollution of Fresno's drinking water supply. Birth defects and other reproductive harm have already been attributed to DBCP; its long-term cancer impact remains to be seen.

During the Reagan Administration, the spotlight was on ethylene dibromide (EDB), used to replace DBCP and also a potent carcinogen and reproductive toxin. Again Americans were told that EDB was vitally necessary for grain fumigation, as a nematocide used on citrus, and for a variety of other purposes. Again, apocalyptic claims about its proposed removal were made by its producers and by representatives of the food industry. Following years of litigation and a series of scandalous closed-door meetings between high-level EPA officials and the regulated industry, a major public controversy and action by several individual states combined to convince then Administrator William

Ruckelshaus to ban the chemical. Interestingly, grain supply did not dwindle and citrus yields did not diminish. Also during the Reagan Administration, heptachlor, a known carcinogen, was found to contaminate much of the milk in the state of Hawaii. Its use had been permitted on pineapples whose leaves were fed to dairy cows. Before this use was finally banned, 90 percent of Oahu's milk had to be destroyed.

During the Bush Administration, the pattern continued. A few years ago, EPA announced its intention to ban the pesticide dinoseb because of highly disturbing test data in laboratory animals demonstrating that it caused deformities of the fetal brain and spine, male sterility and reproductive harm. Representatives of the agricultural industry, particularly from the Pacific Northwest, utilized their political muscle to prevent dinoseb's removal from the market. Again, we were told that the ban of dinoseb would have dramatic adverse economic impacts on the production of caneberries and other crops for which no alternative pest control method was said to be possible. Years later, EPA eventually prevailed in the courts, and dinoseb was removed from the market. The production of caneberries continues unabated.

Perhaps the most notorious case of false claims of "essentiality" is the now well-known case of the growth regulator Alar. Studies linking Alar and its metabolite UDMH to cancer appeared as early as 1973. The EPA proposed to cancel all food uses of Alar in the fall of 1985, but following a series of

private meetings with pesticide industry representatives, its use was allowed to continue. In the spring of 1989, a report issued by the Natural Resources Defense Council documented the health risks posed by Alar and UDMH, especially to infants and young children as a result of children's consumption patterns of apple products at levels ten times or more than that of adults. The Environmental Protection Agency stated that the cancer risks presented by Alar were "unacceptable" and EPA's Administrator "found an inescapable correlation between exposure to UDMH and life-threatening tumors" in laboratory animals. In response, Alar's manufacturer, the Uniroyal Corporation, claimed that Alar's removal from the market would have devastating effects on apple production, yields and quality. Nevertheless, increasing consumer pressure, as well as the threat by Congress itself to ban the substance, finally convinced its manufacturer to "voluntarily" withdraw Alar from the market worldwide. Contrary to industry's claims, since Alar's removal from use, apple yields, price and quality have not diminished.

It is no wonder that public confidence in the food supply has been shaken. It is no wonder that opinion polls consistently show deep-seated public support for reform of the nation's food safety laws. Given this sorry record of crying wolf, claims by industry that purported "benefits" and "essentiality" of known cancer-causing agents must outweigh their health risks should be given short shrift. Rachel Carson was right: "The ultimate answer is to use less toxic chemicals so that the public hazard

from their misuse is greatly reduced." In the short term, strict controls should be placed on residues in order to reduce the threat of cancer and other adverse health effects as much as possible. In the long term, given the vagaries of cancer risk assessment and the overall adverse environmental impact of pesticides, including by contaminating drinking water supplies, the workplace, and rural communities, dangerous chemicals should be phased out of use entirely. Alternative, safer pest control methods should be researched, promoted and used more comprehensively in all sectors of agriculture.

In a report describing EPA's accomplishments, former EPA Administrator William Reilly announced that pollution prevention is the best way to reduce risk. With pesticides, numerous alternative agricultural techniques are already available to reduce the use of these chemicals. Last month, NRDC released Harvest of Hope: The Potential for Alternative Agriculture to Reduce Pesticide Use.¹⁵ This two-year research project revealed that currently available alternative agricultural methods could reduce pesticide applications between 25 and 80 percent in nine U.S. crops.

The promise of alternative pest control remains unfulfilled. Its implementation, which could be greatly enhanced by enactment of the Kennedy-Waxman legislation, with needed improvements. This legislation will not only improve the safety of the food

¹⁵. Curtis, J., T. Kuhnle and L. Mott, Harvest of Hope: The Potential for Alternative Agriculture to Reduce Pesticide Use, 1991.

supply. It will also reduce the increasing threat agricultural chemicals pose to the nation's public health, groundwater, and environment as a whole.

V. NRDC'S SUPPORT FOR PESTICIDE LEGISLATION IS CONTINGENT ON CONGRESS' REJECTION OF ALL EFFORTS TO PREEMPT STATE AUTHORITY TO SET STRICTER PESTICIDE TOLERANCES.

Proponents of legislation which would preempt states' authority to set tolerances say that such amendments are needed to prevent a "crazy quilt" of conflicting legal requirements which complicate or interrupt interstate commerce of agricultural produce. Unfortunately, this assertion lacks an empirical foundation. Experience has revealed that states exercise their authority to set more stringent pesticide tolerances cautiously and only in compelling circumstances.

States have acted to set more stringent tolerances only when faced with extreme federal inertia in the face of ample evidence that public health was not adequately protected by federal tolerances. There are approximately 300 pesticides approved for uses on food. Only two pesticides have been the subject of state efforts to tighten federal tolerances: ethylene dibromide (EDB) and daminozide (Alar).

In both instances where states set tolerances more stringent than the federal limits, many years of federal inaction or ineffective efforts preceded state action. In both instances, compelling evidence was available on the basis of which state health authorities concluded that the risks from these pesticides

were great, particularly for children. Both times the states tried to motivate the federal government to act and probably would have preferred swift and decisive federal action. The EDB and daminozide incidents did not stem from a surplus of conflicting and overlapping authorities to set tolerances. Instead, these events demonstrate the confusion and danger which result from the federal government's failure to exercise its authority to revise tolerances when new data reveal high risks. State authority must be retained as a "fail safe" in the event that the federal government fails to diligently and effectively implement the food safety law.

VI. CONCLUSION

NRDC applauds the Chairman for initiating the review of the pesticide regulatory program. NRDC also believes there is an urgent need for new legislation to streamline pesticide regulation and to ensure that pesticides in food are safe. Legislation of this kind is needed to restore public confidence in our federal programs to protect our food supply. Unfortunately, H.R. 1627, the Lehman-Bliley bill, misses the mark. The Kennedy-Waxman bill would take an important first step towards better protecting the public, although it does need strengthening, as proposed in our Pesticide Reform Agenda. The American public is demanding a vastly safer food supply. We hope to work with this Committee to ensure that the public's demand is heeded.

TESTIMONY OF
JAY J. VROOM, PRESIDENT
NATIONAL AGRICULTURAL CHEMICALS ASSOCIATION
BEFORE THE
SUBCOMMITTEE ON DEPARTMENT OPERATIONS AND NUTRITION
COMMITTEE ON AGRICULTURE
UNITED STATES HOUSE OF REPRESENTATIVES

AUGUST 2, 1993

Mr. Chairman and members of the Subcommittee:

On behalf of the National Agricultural Chemicals Association (NACA), I would like to thank the Subcommittee for this timely opportunity to examine the important and substantial improvements to America's food safety laws suggested by H.R. 1627, the "Food Quality Protection Act of 1993."

NACA is the not-for-profit trade organization of U.S. manufacturers, formulators and distributors of agricultural crop protection and pest control products. Our membership is composed of the companies that produce, sell and distribute virtually all of the active compounds used in crop protection chemicals registered for use in the United States. For this reason, NACA has a special concern for the system which ensures the safety of America's food supply. To further improve upon that system, NACA has joined with the 235 organizations represented by the "Food Chain Coalition" in its support for the objectives of H.R. 1627. We strongly support this bill's elimination of the scientifically outdated Delaney clause, and the concept of replacing it with a single narrative negligible risk definition for both raw and processed foods. Broad

scientific consensus on this fundamental issue has been reached, and it is time for our food safety laws to reflect modern understanding.

In addition to the improvements suggested by H.R. 1627, NACA is prepared to offer some important suggestions which would make our system of pesticide regulation even better, so that our laws reflect advances in scientific understanding and increase public confidence in the safety of our food. Our suggestions for the FIFRA and FFDCA titles of H.R. 1627 include ensuring that pesticide tolerances are adequately protective of infants and children, speeding the cancellation process, resolving the minor use dilemma, examining the appropriateness of maximum tolerated dose testing, clarifying the proper consideration of pesticide benefits, promoting international harmonization and uniformity of tolerances, and resolving the issue of preemption of local pesticide use regulation. With agreement on these issues, and other minor amendments if necessary, NACA is pleased to support H.R. 1627.

PROTECTION OF INFANTS AND CHILDREN

The release last month of the long-awaited Pesticides in the Diets of Infants and Children report by the National Academy of Sciences, National Research Council has focused public and industry attention on the important issues of food safety and pesticide tolerances. NACA takes this report very seriously, and are committed to assisting EPA in further strengthening our food safety system.

Although the NAS report does not recommend or require specific legislation, we support efforts to increase EPA's consideration of

the effects of pesticide residues on specific populations. In that regard, we are pleased that H.R. 1627 addresses the issue of "identifiable subgroups" of food consumers.

The lesson we have learned from the recent Delaney clause debate and litigation is that the level of scientific understanding changes with time. Legislation which attempts to codify science will become obsolete. Specific science-based legislation which directs an agency to act in some particular manner in all instances freezes science and regulation at a particular point in time, and keeps regulation from moving forward with science.

A recently announced study by the NAS is but one example of the critical need to retain regulatory flexibility. On July 23 the NAS announced that it would begin a two-year project to study the impact of naturally occurring chemical carcinogens on human health. The results of that study will very likely be an important part of EPA's ongoing evaluation of human health from ingestion of carcinogens. The legislation considered by the Subcommittee today must be broad enough to allow EPA to take appropriate action to implement whatever science may teach us tomorrow.

Consequently, NACA supports legislation for the protection of infants and children which directs EPA to take action to address areas where data is lacking or current tests are inadequate, while at the same time preserving enough flexibility to allow EPA to use its expertise, and quickly and easily adapt to advancing scientific understanding. We believe that H.R. 1627 is such legislation.

CANCELLATION

The concern expressed by NACA and others regarding cancellation of a pesticide's registration is simple--it takes too long. Unnecessary delays erode public confidence in our products, and in EPA's ability to regulate them. We believe that cancellation can and should be shortened, and herein offer specific proposals to streamline and improve that process.

H.R. 1627 goes a long way toward improving the current process. It calls for peer review of the proposed action, pre-notice to registrants and affected government agencies, advance notice to the public of proposed rulemaking, and notice and comment rulemaking. We strongly support the objectives behind these proposals, but propose going even further.

NACA has two specific recommendations which are designed to increase efficiency and promote fairness in the cancellation process proposed in H.R. 1627. First, we suggest deleting the provision on advance notice to the public of proposed rulemaking. Second, to ensure that EPA is sensitive to a shorter cancellation process, we feel that a one year deadline could be imposed on the rulemaking proceeding. Taken together, these two changes will ensure faster overall cancellation, and restore public confidence in the integrity of the process.

However, any amendments resulting in faster cancellation must go hand-in-hand with the fundamental procedural guarantees of fairness provided by the right to conduct cross examination. Fairness to registrants, pesticide users and the general public demands a thorough investigation of the facts, assumptions and

allegations regarding the characteristics of the product under review.

The right of both parties to conduct cross examination is an important feature of adjudicatory proceedings conducted under the Federal Food, Drug and Cosmetic Act (FFDCA) and the Toxic Substances Control Act (TSCA), among others. FIFRA should provide no less. When appropriately limited to disputed issues of material fact and regulatory alternatives, cross examination can clarify complex and/or contradictory evidence, and should not appreciably add to the overall length of the hearing. Because it is designed to elicit both the strengths and weaknesses of opposing positions, cross examination will assist the Administrator in making a fair determination based on the facts, rather than on the artful presentation of an advocate.

MINOR USE

One of the most vexing and visible casualties of the high cost of reregistration and spiraling maintenance fees has been the loss of several thousand pesticide registrations. Roughly one-half of some 40,000 formulated product registrations have been voluntarily dropped over the last four years. Unfortunately, many of those registrations were for use on the \$30 billion dollar per year misnomer--"minor use"--crops. The harsh economic reality of product registration and reregistration costs simply does not make it feasible to retain an adequate number of minor use registrations.

We are encouraged by the leadership of Chairman de la Garza, and the efforts of many members of this Subcommittee, for your

commitment to address and resolve this problem through introduction of H.R. 967, the "Minor Crop Pesticides Act of 1993." Invaluable input during last month's hearing from groups such as the Minor Crop Farmers Alliance (MCFA) has helped focus attention on creative and workable solutions. NACA believes that additional time for exclusive use of data, a clearer definition of minor use, increased regulatory flexibility, funding for IR-4, better inter-agency coordination, and consideration of "minor use" impact when setting tolerances will be essential components for successful resolution of this issue.

NACA supports the objectives of H.R. 967, and we look forward to working with this Subcommittee, the MCFA, and the Food Chain Coalition to make H.R. 1627 more responsive to growers who risk losing some of their most important production tools.

MAXIMUM DOSE TESTING

Recently, much attention has been focused on the manner in which EPA evaluates substances for carcinogenic potential. Under optimal circumstances, the carcinogenic potential of substances and the risk to humans from low levels of anticipated exposure should be evaluated based on a combination of epidemiological, mutagenicity, structure-activity relationships, and/or chronic rodent bioassay considerations.

Under current EPA regulation and policy, rodent bioassay are the primary mechanism used to assist in the evaluation of human risk. Therefore, the maximum tolerated dose ("MTD," also known as highest dose testing, or "HDT") used in rodent carcinogenicity studies should be changed to a level which can reliably predict the

possible occurrence of cancer at doses to which humans are likely to be exposed. In practice, this means identifying a meaningful dosage level at which the test animals' general health is not compromised by effects other than cancer. The current practice of using excessive doses to compensate for small group size of rodents and/or statistical insensitivity is scientifically irrational and must be reexamined.

Instead, NACA believes that HDT should:

- ▶ Be a level at which the physiological responses and organ functions of animals treated will not differ from those observed in unexposed animals;
- ▶ Not disable normal body defenses including metabolic, immunologic, and/or genetic repair, which operate at relevant human exposure levels;
- ▶ Not produce biochemical distortions which result in, or cause, cellular injury, accelerated cell replication, toxic hyperplasia or toxicity-induced cancer;
- ▶ Not alter the metabolism of test substance from that seen at other doses, including the lowest dose tested. This avoids the formation of metabolites which are not produced at dose levels relevant to human exposures;
- ▶ Be relevant to possible human exposure with a maximum of 1000-fold safety margin and selected on the basis of short-term testing; and
- ▶ Not produce overt toxicity, or adversely affect nutrient utilization.

Consequently, HDT should be chosen as the highest non-toxic dose that can be expected to yield results relevant for human risk

assessment. High doses which cause excessive toxicity are not appropriate. Therefore, in light of the dubious scientific value of such data, the results from such tests done in this manner should be excluded for risk assessment purposes.

NACA has advocated reforms in the HDT concept for some time. In comments to the National Institute of Environmental and Health Sciences, NACA offered its support for the conclusions of the National Toxicology Program Board of Scientific Counselors that the criteria for selection of the high dose used and the default criteria used need to be re-evaluated.

Scientific evaluation has not been limited to experts in the United States. Because of concerns over the use of HDT, the Commission for the European Communities is currently giving serious consideration to a proposal to re-evaluate "the long-term toxicity and carcinogenicity of all active substance[s]..." The proposal states conclusively that "[h]igher doses, causing excessive toxicity and necessary to determine the Maximum Tolerated Dose, because of difficulties in interpreting the data generated, and in extrapolating results obtained to man, if included to meet other regulatory requirements, are not considered relevant to evaluations..." (emphasis added).

Additionally, the 24 developed-nation members of the Organization for Economic Cooperation and Development (OECD) published a statement following their workshop last October including HDT as an issue which deserves international attention, and forecasting the need for agreement on criteria to identify high dose issues prospectively.

BENEFITS

The issue in the legislative debate over benefits is not about whether pesticides have benefits, for they certainly do. The debate instead concerns how data on the benefits from use of the pesticide should be used to determine whether certain risks are acceptable, how one product should be evaluated vis-a-vis another, or how one product compares with another technology.

As part of the registration process, current law properly provides for the evaluation of the risks and benefits of a pesticide. A fair evaluation of any risk necessarily includes an assessment of the benefit to be derived from acceptance of the risk. The Kennedy-Waxman legislation would eliminate the benefits side of that currently balanced equation, making issuance of a pesticide tolerance a "risk-only" decision. Ignoring benefits means that decisions involving pesticide use are made out of context, and distorts our understanding of risk. We believe that to be ill-advised.

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NACA supports the general principles for evaluating the risks and benefits of pesticide residues set forth in H.R. 1627. The risk-benefit approach is fair to registrants, and recognizes that reasoned, informed decisions can not be made in a vacuum. However, even that provision could be improved by a clear articulation of the kinds of benefit data EPA needs in order to make its decisions. Development of better information on use patterns of particular pesticides (beyond the major crops) would also be a great help. More accurate and complete information on pesticide usage would restore public confidence, and allow risk-benefit decisions to be made more easily.

On a related matter, NACA wishes to correct the record on a misstatement by the NAS in its report on the effects of pesticides in the diets of infants and children. The NAS report incorrectly states in several places that pesticide tolerances are established based upon agricultural, rather than health, considerations. This is patently false. Even a cursory review of the numerous tests, data and studies which manufacturers are required to submit in support of a registration (set forth fully in the Code of Federal Regulations) reveals that health and safety considerations are the factors considered by EPA in granting a registration and setting tolerance.

INTERNATIONAL HARMONIZATION/UNIFORM TOLERANCES

NACA is pleased that H.R. 1627 addresses the important role which international harmonization and national uniformity of tolerances can play in increasing efficiency, confidence in regulation, and the promotion of high standards.

Tolerances established by the Codex Alimentarius Commission are subject to standards which are generally as strict, and in some cases more so, as those in the United States. Where appropriate EPA should be required to harmonize our tolerances with those established by the Codex Commission. Where departures (higher or lower) are appropriate, EPA should be able to support that departure with reliable scientific data and rationale.

As with international harmonization, the promotion of nationally uniformity for tolerances leads to increased public protection, and confidence in the safety of the food supply. NACA supports the concept of nationally uniform tolerances for most

pesticide products. With limited exceptions, states should be precluded from setting differing tolerances.

PREEMPTION

Consistency and uniformity in pesticide use regulation is a major goal of NACA. Because independent regulation of pesticide use by even a small percentage of the 83,000 units of local governments would create confusion and hinder the delivery of effective pest control and crop protection, NACA has been an active member of the Coalition for Sensible Pesticide Policy (CSPP), which supported the Federal-State Pesticide Regulation Partnership Act of 1991.

The existing regulatory authority of Federal and state governments under FIFRA provides adequate opportunity for safe and effective regulation of pesticide use. Attempts by over 100 local governments to independently regulate pesticide use over the past few years clearly show the need for this legislation.

With other important federal and state demands placed upon them, local governments often lack access to sufficient financial and technical resources, scientific expertise and fundamental experience in pesticide regulation. Because of the regulatory partnership established under FIFRA, states and the Federal government have already developed expertise and experience in this area. In several instances local governments have passed regulations which either conflict or overlap with existing legislation, requiring costly resolution of these conflicts in court. In the meantime, farmers and others whose businesses require the use of EPA-registered pesticides face uncertainty and

possible legal sanction for trying to comply with this growing regulatory morass.

CONCLUSION

NACA looks forward to working with this Subcommittee, and all parties interested in improving our food safety laws and pesticide regulatory program.

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STATEMENT OF

WILLIAM D. GULLICKSON, JR.
CHAIRMAN, CHEMICAL PRODUCERS AND DISTRIBUTORS ASSOCIATION

I am Warren E. Stickle, President of the Chemical Producers and Distributors Association (CPDA) and I am accompanied by Bill Gullickson, President of McLaughlin, Gormley King Company (MGK) in Minneapolis, Minnesota & Chairman of CPDA's Board of Directors. We appear before members of the House Subcommittee on Department Operations and Nutrition to discuss a number of pesticide issues of importance to our association.

By way of introduction, the Chemical Producers and Distributors Association is a voluntary, non-profit membership association consisting of about 100 member companies engaged in the manufacture, formulation, distribution and sale of some \$4.0 billion worth of products used on food, feed and fiber crops, and for lawn, garden and turf care.

Before I share with you some of our thoughts on H.R. 1627, the "Food Quality Protection Act of 1993," I would first like to commend you, Mr. Chairman, for holding FIFRA hearings over the past two months. Your efforts have gone a long way to raise the level of awareness with regard to the complexities of regulating pesticides.

I would now like to turn to H.R. 1627 and focus, in particular, on those provisions of the bill which deal with cancellation and suspension under FIFRA, the concept of negligible risk in setting tolerances for pesticide residues in foods under the Federal Food, Drug and Cosmetic Act (FIFRA), and the definition of a pesticide.

I would also like to discuss several related issues. These include a set of recommendations for the expedited review of "me-too" pesticide registrations and simple label amendments - commonly referred to as "fast track," the need for label reform within EPA, and the need to preserve an important class of pesticides utilized in public health programs.

CPDA Supports H.R. 1627

We at CPDA strongly support H.R. 1627, the "Food Quality Protection Act of 1993." The bill would create a single negligible risk standard for tolerances for pesticide residues in raw commodities and processed food. EPA would be responsible for defining negligible risk in light of evolving science, taking into account different routes of exposure to a pesticide and sensitivities of population subgroups. EPA would be required, where reliable data are available, to calculate the dietary risk posed to food consumers by a pesticide on the basis of the percent of food actually treated with the pesticide and the actual residue levels of the pesticide that occur in food.

The U.S. Court of Appeals for the Ninth Circuit ruled in Les v. Reilly on July 8, 1993 that Section 409 of the Federal Food, Drug, and Cosmetic Act, the "Delaney Clause", requires EPA to apply a "zero-risk" standard for carcinogens when setting permissible tolerances for pesticides in processed food.

The Les ruling could have a disastrous effect on the abundance and safety of our nation's food supply and the agrichemical industry as a whole. The decision could lead to the cancellation of thirty-five different pesticides, which comprise more than 10 percent of the basic pesticide ingredients used in agriculture, and hundreds of different uses which were previously approved by EPA.

In 1958 Congress passed the Delaney Clause, which states, in part, that "no additive shall be deemed to be safe if it is found to induce cancer when ingested by man or animal." EPA had previously construed this clause using a de minimis standard for pesticide residues in processed food.

Under the de minimis standard a tolerance was granted if the human dietary risk from a pesticide was so remote that the threat of contracting cancer was "at most negligible." The Ninth Circuit, however, has interpreted the Delaney language "found to induce cancer" to mean no traces of carcinogens in residues for processed food, regardless of how borderline the response in test animals or how marginal the risk may be to consumers.

The "zero risk" Delaney standard is simply unworkable for establishing reasonable risk evaluation. When Delaney was promulgated, almost thirty-five years ago, the usual scientific testing standards measured in the parts per million. Scientific detection standards now measure in the parts per trillion and greater, resulting in the detection of carcinogens which present,

at the most, a remote and negligible threat to the public.

A mass revocation of these pesticides will likely lead to fruit, grain, and vegetable price increases and a decline in the quality of our food. A subsequent reduction in the consumption of these products by our citizens could lead to the erosion of our health and the nutritional integrity of our diets. The American Cancer Society strongly maintains that Americans need to double their present consumption of fruits, vegetables, and fiber to reduce the incidence of various types of cancers. Implementation of a "zero-risk" Delaney clause would therefore likely increase the incidence of cancer across the country.

The EPA has a vast wealth of resources, personnel, and scientific knowledge it uses to draft pesticide policy. As a federal agency it has the regulatory discretion to interpret statutes in order to effectuate this policy. EPA has long determined that a "negligible risk" standard most effectively protects the health of the American consumer and maintains the abundance of our nation's food supply.

To avoid the unnecessary cancellation of numerous valuable pesticides, Section 409 of the FFDCA should be amended to reinstate the flexible concept of "negligible risk" when setting permissible tolerances for pesticides in processed food.

Cancellation

During the continuing discussion about the need for food safety reform, the process and procedures by which the Environmental Protection Agency cancels or suspends a product is at the heart of the need to revamp our pesticide regulatory program.

We support the Environmental Protection Agency's need to move quickly to remove problem pesticides from the marketplace especially since the process includes the special review process (Informal Rulemaking), the cancellation hearing, and finally, judicial review in the courts.

We also agree that the experience of the last fifteen years has clearly demonstrated that the cancellation process has taken too long, with some products taking more than a decade to remove from the marketplace. The average has been five years and this length of time is still too long.

While CPDA supports an effort to abbreviate the regulatory process, we must keep in mind the need for an adequate scientific review of the salient issues: Is the hazard information correct? How much exposure is there to the pesticide? What is the most appropriate way to reduce the risks?

We strongly support the cancellation provisions of H.R. 1627.

The bill would streamline and amend the cancellation provisions of FIFRA with its elimination of the current formal adjudicatory hearing requirement. In its place, the legislation would provide for scientific committee peer review of the evidence supporting proposed cancellation, pre-cancellation notice to pesticide registrants, HHS and USDA, advance public notice and comment on proposed cancellation actions, FIFRA Scientific Advisory Panel (SAP) review of cancellation proposals and the right to an informal cancellation hearing.

In addition, H.R. 1627 allows for judicial review, thereby ensuring protection of due process. In short, the cancellation provisions of H.R. 1627 will enable us to respond quickly to possible problems without making bad decisions which are based on incomplete information or emotion.

Suspension

We strongly support the suspension provisions in Section 104 of H.R. 1627. We believe that there is no need to change the suspension provisions of FIFRA, since no one has clearly demonstrated that the current suspension authority has not worked. In fact, suspension authority has only been utilized three times in the last twenty years. Other factors such as the escalating data requirements, the considerable care in registering products, the comprehensive reregistration of all products, including old chemicals, and the use of means short of suspension, are really working.

Suspension is an emergency procedure that advocates for change would like to see misdirected to non-emergency matters. In an atmosphere of fear and emotion, it may be difficult to achieve reasonable and practicable solutions with accurate, scientific, and fact-based decisions. An "easier" suspension authority would subvert the cancellation process by encouraging EPA to use the "path of least resistance."

We at CPDA believe there are four compelling reasons not to change the suspension provisions of FIFRA:

First, the cancellation provisions contained in Section 102 of H.R. 1627 now before this Subcommittee completely restructure and expedite the procedures for removing "problem" chemicals from the marketplace.

Second, the passage of the 1988 FIFRA "Lite" amendments contained an indemnification process which passed most of the financial burden to the registrant, thus removing a remaining requirement that EPA indemnify pesticide owners for losses incurred by taking a product off the market.

Third, under Section 6 (c), the Administrator has enormous

existing powers within FIFRA to utilize emergency procedures to suspend a product without prior notice, hearing or delay, to immediately stop the sale and use of a dangerous pesticide, if there is an imminent hazard.

Fourth, no one, not even EPA, has made a case that the existing suspension authority has not worked properly, and needed to be "fixed."

Changes in the FIFRA suspension provisions could also have several important disadvantages:

1. It would encourage action based on glamorous appeals of movie stars and pressure groups, on "sound-bite" journalism, and not on scientific facts.
2. Suspension, even if temporary, or for a short time, without an opportunity for a public hearing or a fact based decision-making process, will effectively destroy the product and its public credibility.
3. Modified suspension authority will cause a sudden loss of valuable pesticides, resulting in unexpected losses to farmers and ranchers, perhaps even including crops yet to be harvested.
4. Agrichemical producers, distributors, dealers and users will be exposed to costly and unexpected economic losses, resulting in unacceptable business risks to registrants who are deciding on future research investments.
5. Insistence on suspension amendments will block progress and further compromise on other FIFRA amendments, will unnecessarily increase litigation, and will undermine the risk vs. benefit evaluation in FIFRA.

In summary, we favor expediting the cancellation process so that we can remove problem chemicals from the marketplace in a timely manner. Conversely, we oppose any changes in the suspension provisions of FIFRA as unnecessary and unneeded.

Additional Provisions of H.R. 1627

We strongly support Title II of H.R. 1627 that establishes procedures for the collection of pesticide use information. The legislation would direct USDA to collect pesticide use data of statewide or regional significance for all major crops and crops of dietary significance. Also, the bill calls for coordination between EPA and USDA to assure that the data is appropriate for exposure and benefits calculations in connection with pesticide tolerance decisions.

The USDA is to be commended for its new data collections program it has undertaken during the last three years. By collecting residue data at regional warehouses and product distribution centers, the department is able to collect residue data on fruits and vegetables just before these commodities are sent to grocery stores. Rather than making assumptions above residue levels, based upon pesticide applications, we are able to obtain a more realistic account of the actual residues, if any, that are on the fruits and vegetables. The closer we get to the grocery store, the more accurate and realistic statistics we can gather.

Also, we strongly support the Integrated Pest Management (IPM) provisions of Title II, Section 202, that encourages the EPA and USDA to "research, develop and disseminate Integrated Pest Management techniques..."

In addition, we also support the international harmonization provisions of Title III, Section 305(j), which would require the EPA to take into account the CODEX recommended international residue limits (MRLS) and to explain any departure from the CODEX limits.

Lastly, we strongly support the provisions on the national uniformity of tolerances as contained in Section 305(l). We can not promote interstate commerce in food products if we allow 50 states and 83,000 local political subdivisions to establish their own tolerance levels. This provision of H.R. 1627 precludes states and political subdivisions from issuing tolerance limits, or warning requirements or other restrictions on pesticide residues in foods, different from those set by EPA for pesticides registered or reregistered by EPA after April 25, 1985. A state may, however, petition EPA for approval of a different tolerance limit on the basis of compelling local conditions.

INERTS

Although we strongly support H.R. 1627, we have some real concerns about shifts in the definition of a "pesticide chemical" and a "pesticide chemical residue" as contained in Section 302(a) of Title III - Amendments to the Federal Food, Drug, and Cosmetic Act.

As presently written in H.R. 1627, a "pesticide chemical residue" is defined as a residue of a pesticide chemical, including its active ingredients and inert ingredients. Under present FIFRA, inert ingredients are not included in this definition.

Thus, if the language is adopted, we would establish one definition of a pesticide which EPA uses under FIFRA, and another expanded definition for use by FDA under FFDCa.

Under these definitions, future residue testing could include testing for metabolites as well as all inert ingredients. All present residue testing for the reregistration of particular crops could be invalidated for hundreds of pesticides and thousands of uses. These residue testing studies for key metabolites (not inerts), costs an average of about \$150,000 per crop use. By adding inerts, the cost could jump \$50,000 to \$100,000 for each crop use. Importantly, there is no distinction between the four categories of inerts, and no emphasis placed on inerts of toxicological concern. By potentially driving up the cost of residue testing on all crop uses, we place the American pesticide industry and the farmer at a serious disadvantage in a competitive world marketplace.

We respectfully request that the term "inert" be deleted from Section 302(a) which seeks to amend FFDCA's Section 201(a).

EPA PESTICIDE REGISTRATION AND REREGISTRATION PROGRAMS

While the Agency has expressed considerable concern and expended much energy about the necessary funding of its programs, it has not spent a commensurate effort at implementing the 1988 FIFRA "Lite" programs. Though the Agency has collected millions of dollars in fees, it has not fully implemented its regulatory program in a timely manner. We at CPDA would like to take a moment to discuss: 1) Fast Track; and, 2) Label Changes, and 3) the Funding of the Registration and Reregistration programs.

Fast Track

For almost five years, the EPA has been implementing the provisions of the 1988 FIFRA "Lite" amendments, but has not been able to clear the backlogs that exist in the registration division. This backlog especially impacts "fast track" or "expedited review" products, despite Congressional authorization for up to \$2 million per year of reregistration maintenance fees to be used to implement fast track.

During the 1988 legislative debate over the FIFRA amendments, we at CPDA strongly supported the provisions for an expedited review of "me-too" products and label changes. As formulators and distributors of generic end-use products, this expedited review provision was the most important aspect of the registration process to our segment of the pesticide industry.

We have been disappointed by the failure of the Agency to fully implement the "expedited review" process. On the front-end review process, the Agency has done an adequate job of reviewing the original documents and determining if they are in order and complete. This initial review has usually been completed in forty-five days. The second phase -- requiring ninety days -- provides for the finalization and approval or rejection of an "expedited

review" application. It appears that "an expedited review" product gets no special handling in this second phase. It seems simply to go to the bottom of the pile. We believe EPA should utilize a two stack approach -- one stack for "expedited review" and another for all other products, with appropriate EPA personnel assigned to each.

The so-called ninety day second phase has taken anywhere from six to eighteen months, with some isolated examples that required more than two years. One small company has waited more than three years for an amendment to a "me-too" label, but during this time has had to amend its label three more times and still has not gotten the product registered.

The Agency has not moved quickly enough to solve these "fast track" problems. Some simple label changes, such as alternative brand names or the addition of alternate sources of supply to a confidential statement of formula, that take fifteen minutes to review, instead, take six months to filter through the process. Many label changes need only prompt responses, without delegation of responsibility. We see little evidence that the Agency has moved quickly enough to put the appropriate personnel in place to handle this workload. The Agency has not effectively spent the funds nor spent a proportional share of the maintenance fees to address this pressing problem. We have no accounting on how the EPA spent \$2 million in FY92 on fast track.

We at CPDA would like to offer some suggestions on how to correct some of the problems associated with the expedited review situation.

First, we believe that the resources within the expedited review program should be used to hire or assign an expedited review person for each of the eleven project managers, so that the applications can be reviewed in a timely manner.

Second, although expedited review applications are "coded," we recommend that the applications for fast track should be color-coded so that they can be easily recognized by EPA officials.

Third, if the Agency misses the 90-day deadline for completing the review, then it should give the registrant an update every thirty days until the pesticide is registered.

Fourth, CPDA would like to see a notification system set up for identical me-too products, patterned after notification section 5 of TSCA. Under the rule, if EPA does not respond within 90 days, the me-too product can be marketed. The proposed language could read similar to the TSCA provision.

Label changes not requiring a scientific review, such as a simple revision to wordings of a precautionary use statement,

should also fall under the notification process.

CPDA believes EPA should provide the registrant written confirmation upon receipt of a registrant's notification. A registrant could provide a self-addressed, stamped post card which could be mailed to the registrant upon receipt of the notification. This will help the registrant when it deals with state registration officials, (i.e., California), which require written confirmation of registration.

Fifth, as an alternative approach to the above mentioned notification plan, the Administrator could establish a standard for "me-too" products and label changes, and establish specific regulatory procedures for the registration of these products. A rule could:

- (A) identify all substantive and procedural requirements which must be met in order to market a "me-too" product or make a label change.
- (B) create record-keeping for documents demonstrating compliance with these requirements; and,
- (C) create a mechanism for assigning to each such product an individual identifying registration number for record-keeping and reporting purposes.

A substantially similar or identical product could be deemed to have been registered upon notification by the registrant to EPA by registered mail of the name of the product and certification by the registrant that the requirements of this subsection have been met. A stamped approval label must be returned to the registrant within 30 days of such notification.

Sixth, it is important to reduce the amount of redundant and unnecessary testing for "me-too" products, and reduce the amount of acute toxicity testing by batching the available test data for substantially similar products.

Seventh, we recommend that the "out year" of the program -- FY95, FY96 and FY97 -- be required to allocate a full \$2 million per year toward expedited review, something they were directed to do in 1988 but have apparently never done.

Label Changes

Several different offices and programs within the EPA's Office of Pesticide Programs (OPP) require, at different times, changes on a pesticide product's label. Some of these EPA mandated changes might be to change an ingredient, an inert, or a use. Sometimes a label might need to reflect some new set of directions or warnings about use or specific health and safety instructions. Sometimes

the Agency may require that the registrant reshape the label or reduce its size, or place new instructions for proper disposal of the container on the label.

Specific programs also address specific needs to change the label, such as the Endangered Species Program, container rinsing proposals from the new FIFRA "Lite" requirements, and other programs. The Label Improvement Program (LIP) also seeks to update the label and make appropriate changes. In addition, label changes may be requested from the Air and Water Divisions of EPA to conform with the Clean Air and Water Acts. Many different offices and programs require the registrant to make changes on label, but no one part of the Agency coordinates appropriate label changes. These various programs do not know what the other parts of the Agency are doing about label changes.

A company frequently makes a label change in response to an EPA office's request, and prints thousands of new labels, only to find that another EPA office, program, or division is requiring additional changes. Many companies print up new labels just in time to throw them in the trash. It can be an expensive, time-consuming and frustrating experience and means money and jobs for many small businesses who are fighting to compete in a tough market.

To give you some idea of the magnitude of this problem, a random sampling of CPDA companies indicates that, on average, they spent in excess of \$808,600 over the past 6 years on labels which were ultimately discarded. For these companies, this translated to approximately 5,600 wasted man-hours and represented more than 1,613,000 labels which never saw the light of day. When one extrapolates these figures to the entire industry, it becomes very apparent that a problem exists which needs to be addressed quickly.

A number of CPDA member companies cite a definite lack of coordination between product managers, Label Improvement Program (LIP) personnel, and other Agency staff in formulating label requirements. Representatives of one CPDA member company, for example, report that they have been required to write the Confidential Statement of Formula (CSF) for the same pesticide in different ways for different EPA personnel. This same company also notes that it has received conflicting instructions from various Agency personnel regarding the wording of the Precautionary Statements found on phenoxy labeling.

Other OPP programs which affect reregistration, the container disposal program, the regulation of inerts, farm worker protection standards, certification and training requirements, and product reclassification will certainly have an impact on the fate of present labels or the re-labeling of existing stocks.

One small-sized formulator of lawn and garden products

responds that it seeks to reduce waste in its labeling operations by printing small quantities of labels on a more frequent basis. However, the company also notes that it is then faced with the disadvantage of having to pay a significantly higher unit cost per label. In these troubled economic times, a small business cannot afford to incur such needless and unnecessary costs.

In an effort to improve the way in which the Agency handles label revisions, we at CPDA offer the following suggestions which we feel will consolidate and better time EPA's labeling regulatory activities.

First, one office in OPP, within the Registration Department, should coordinate all label changes from all programs, all product managers, and all divisions so that there is no confusion about the necessary changes needed to comply with EPA's mandates. At present, many different offices and programs require the registrant to make changes on the label, but no one part of the Agency coordinates appropriate label changes.

The Agency has made considerable strides in coordinating this effort. However, problems still exist. For example, in EPA's negotiations with the 2,4-D Task Force it agreed that existing 2,4-D labels would be used until June 15, 1994, after which a label change would be required. However, for these same products EPA's mandated label change date for PR Notice 93-3 wetlands language, PR Notice 93-6 heightened efficacy language and PR Notice 93-7 Worker Protection standards language is April 24, 1994. The Agency coordinated the dates for the three PR Notices. However, it neglected to determine what other label changes were being implemented and at what date. The oversight will essentially result in the shortening of the 2,4-D deadline a month and a half from June 15, 1994 to April 24, 1994.

Second, one date each year should be selected for all EPA-mandated label changes. We suggest October 1st as a good date because it represents the end of the growing season as well as the beginning of the new fiscal year. All label changes could be effective on this date, so that companies can start production in the fourth quarter for the following Spring's use.

Third, companies need enough lead time to implement the Agency's requirements for both new product labeling and for the re-labeling of existing stocks. We propose that the Agency provide companies with at least a year's notice to adopt EPA-mandated label changes.

Of course, CPDA understands that there will be cases involving an imminent hazard or some other emergency situation where an immediate change on product labeling is merited. In those instances, we believe that the Administrator of EPA should be given adequate flexibility to implement the necessary labeling

requirements outside of the time schedule set forth in CPDA's recommendations above.

CPDA believes that this labeling proposal, if adopted, will not only save industry time and money, but will eliminate duplication of effort within the Agency and enable EPA to channel its valuable technical resources into other beneficial program areas.

We applaud this Subcommittee's effort last May 17th when it included this label proposal in the "en bloc amendment" provision to H.R. 3742, introduced by Congressman Charlie Rose. We strongly urge your inclusion of this amendment in any FIFRA bill that is reported in the 103rd Congress.

PUBLIC HEALTH PESTICIDES

CPDA would now like to share some thoughts on a very important class of pesticides -- specifically, minor use pesticides utilized in public health programs to control and eradicate the spread of disease - carrying insects and pests which threaten our health and well-being.

CPDA strongly supports H.R. 1867, the "Public Health Pesticides Protection Act of 1993" introduced in this 103rd Congress by Representatives Calvin Dooley (D-CA) and Wally Herger (R-CA). The legislation ensures that EPA establish guidelines that take into consideration the need for and benefits of public health pesticides used to combat disease-carrying insects and pests and to ensure that these products are not lost in the reregistration process due to economic reasons alone.

The Dooley-Herger bill contains provisions which would:

- o Define public health pesticide uses in the context of minor uses;
- o Create a separate class of pesticide registration for public health pesticides with a risk-benefit balance, which is separate from that utilized for agricultural pesticides;
- o Require that the EPA Administrator take into consideration "the differences in concept and usage" between agricultural, non-agricultural, and public health pesticides;
- o Require consultation by the EPA Administrator with the Secretary of Health and Human Services on pesticides for public health uses, similar to the existing consultation between EPA and USDA; and,

- o Expedite the registration of products necessary for the protection of public health.

On April 23, 1991, Dr. William Hazeltine, Manager-Environmental of the Butte County Mosquito Abatement District in California, appeared before members of the House Subcommittee on Department Operation's Research and Foreign Agriculture to discuss the benefits of public health pesticides. More recently, he appeared before this panel during the June 8, 1993 oversight hearings on FIFRA conducted by Congressman Charles Stenholm, Chairman of the Subcommittee on Department Operations and Nutrition. During each of his Congressional appearances, Dr. Hazeltine eloquently drew attention to the need to create a public health provision in FIFRA, with an emphasis on controlling diseases transmitted by mosquitoes and other vectors.

Dr. Hazeltine's June 8th testimony states, "...It should be obvious that for good mosquito and other vector control programs to continue, professional Public Health Decision-makers need to have a wide array of choices available to them, so they can select the best material or method for use when control becomes necessary. If pesticides are not registered by the Federal Environmental Protection Agency (EPA) they are not going to be available for use to protect the Public's Health. While we continually look at a wide range of control alternatives, we recognize the need for effective pesticides which are registered and available for our use."

I would also like to point to the comments of Dr. John Graham shared with this Subcommittee on July 14, 1993. As members of this Subcommittee know, Dr. Graham is Professor of Policy and Decision Sciences at the Harvard School of Public Health and founding Director of the Harvard Center for Risk Analysis.

Dr. Graham's July 14th testimony makes a very convincing case for the human health benefits associated with the use of many pesticides. He states, "...In some situations, the loss of a pesticide may cause direct harm to public health as a result of consumer exposure to the fungi that thrive without the pesticide. For example, although many fungicides have been shown to cause cancer in animals at high doses, some of the toxins produced by fungi, such as aflatoxin, are also known to cause cancer. One of the benefits of pesticides is the human health protection resulting from destruction of fungi."

Many CPDA companies manufacture, formulate and distribute insecticides and rodenticides that attack mosquitoes, flies, ticks, mites, fleas and other insects, rats and other rodents, and that promote public health. Many of these companies, therefore, emphasize non-agricultural pesticide production and public health issues. Because we share the concerns expressed by Dr. Hazeltine

and Dr. Graham with regard to public health issues, we at CPDA believe that the public health pesticide provisions of H.R. 1867 should be adopted as an amendment to FIFRA.

In summary, the Dooley-Herger bill recognizes the unique benefits of low volume minor use pesticide products which are widely used in public health programs to combat a host of insects and pests which transmit harmful diseases to man. It is critical that a wide variety of product choices be made available in order to maintain good mosquito and other vector control programs. Without proper public health programs, vector borne diseases such as malaria and yellow fever might once again become epidemic in the United States. The Dooley-Herger bill will help ensure that this never happens.

PREEMPTION

We at CPDA would like to express our support for legislation which would preempt local jurisdictions from enacting their own rules governing the sale and use of pesticide products. We believe that such regulatory authority over pesticides should be limited to a partnership between Federal and State governments which have the appropriate mechanisms in place to promulgate uniform, sensible regulation based on sound science.

On June 21, 1991, the Supreme Court issued its decision in the case of Wisconsin Public Intervenor v. Mortier. In its opinion written by Justice White, the Supreme Court ruled that local jurisdictions are not preempted by FIFRA from enacting their own pesticide ordinances. In essence, the Court's decision threatens to undermine the existing Federal-State partnership of pesticide regulation by opening up the field of regulation of these products to more than 80,000 units of local government.

At its May 1992 FIFRA markup of H.R. 3742 (the Rose bill) during the 102nd Congress, the DORFA Subcommittee adopted an amendment which preempted local municipalities from regulating the sale or use of pesticides.

This year, Representatives Harold Volkmer and Robert F. Smith are expected to introduce similar legislation. We at CPDA commend Representatives Volkmer and Smith for their leadership on the preemption issue during the 103rd congress. We remain committed in our support of legislation which would amend FIFRA to prohibit the local regulation of pesticides.

Conclusion

We at CPDA greatly appreciate this Subcommittee's efforts to hold this hearing on important FIFRA issues. We strongly support H.R. 1867, the "Food Quality Protection Act of 1993" for its treatment of Delaney, as well as its provisions regarding

cancellation, suspension, data collection, IPM, international harmonization, and national uniformity of tolerances. We do, however, believe that the definition of a "pesticide chemical" as currently written in the bill needs to be changed to delete inerts.

We support H.R. 1627, the Dooley-Herger bill on public health pesticides. We also urge your support for the yet-to-be-introduced bills by Representatives Volkmer and Smith on preempting local jurisdictions from regulating the sale and use of pesticides, and Congressman Steve Gunderson on the synchronization and coordination of data between Federal and State agencies. In addition, we support Chairman E. ("Kika") de la Garza's minor use bill (H.R. 967), except for the provisions on patent term extension and ten years of exclusivity. Finally, we strongly support fixing the registration and reregistration process so that products can be handled in an efficient, effective and expedited manner.

We applaud the Subcommittee for its leadership on pesticide issues and look forward to working with you during the 103rd Congress.



The Soap and Detergent Association

Revised

TESTIMONY OF GERALD R. PFLUG, Ph.D.

PRESIDENT

THE SOAP AND DETERGENT ASSOCIATION

REGARDING THE STATUS OF ANTIMICROBIAL PRODUCTS

UNDER

THE FEDERAL, INSECTICIDE, FUNGICIDE AND RODENTICIDE ACT

BEFORE

THE SUBCOMMITTEE ON DEPARTMENT OPERATIONS AND NUTRITION

OF

THE HOUSE COMMITTEE ON AGRICULTURE

AUGUST 2, 1993

Mr. Chairman and members of the committee, my name is Gerald R. Pflug and I am president of The Soap and Detergent Association (SDA). The SDA is a 139 member national trade association representing the formulators of soaps, detergents and household cleaning products and those companies which supply ingredients to the detergent and cleaning products industry. SDA's members include nationally prominent as well as less well known small, often family-owned, companies. Along with well known formulators of highly visible consumer products, SDA members also include the formulators of industrial and institutional products used in hospitals, nursing homes, hotels, restaurants and public buildings. Over 90% of the cleaning products sold in the United States are made by SDA members.

The products of SDA members have a long history of contributing to the maintenance of public and personal health standards which are, unfortunately, often taken for granted in our country today. Clean clothing, bedding, cooking utensils, plates, silverware, kitchen and bathroom fixtures are, in fact, the broad base on which our exceptional standard of public health rests. The SDA is here today because of its concerns for one of the most important contributors to our high cleanliness standards: antimicrobial and disinfectant cleaning products.

Under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), antimicrobial and disinfectant cleaning products are regulated as pesticides by the Environmental Protection Agency (EPA) because they are intended for preventing, destroying, or mitigating harmful micro-organisms, viruses and bacteria. Common, well-recognized examples of such products include certain brands of

Testimony of G.R. Pflug, Ph.D.
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chlorine bleach (when such claims are made), Lysol Disinfectant Cleaner and Comet Cleanser. Less well known, though equally important, are the myriad commercial products used in business establishments, public accommodations and public buildings.

I am here today on behalf of SDA's antimicrobial/disinfectant products sector because this beneficial category of products faces a number of regulatory problems which we believe ought to be addressed through reform of the FIFRA process. The principal problems of concern are the following:

1. The approval process for new active ingredients needs improvement. No new active antimicrobial agents have been approved in seven years.
2. The process for registering or re-registering products is so cumbersome and attenuated that such processing may require up to two years to complete.
3. Approval of simple label changes may take nine months or more.

The consequence of these regulatory logjams has been to impede the development and introduction of additional safe and efficacious antimicrobial products in the market place. We believe the underpinning for resolution of these regulatory problems already exists in FIFRA.

FIFRA Section 25(a)(1), reads as follows:

Regulations.-The administrator is authorized in accordance with the procedure described in paragraph (2), to prescribe regulations to carry out the provisions of this subchapter. Such regulations shall take into account the differences in concept and usage between various classes of pesticides and differences in environmental risk and appropriate data for evaluating such risk between agricultural and nonagricultural pesticides. (Emphasis added).

If antimicrobial and disinfectant products, as a subset of nonagricultural products, were distinguished under FIFRA and provided a separate regulatory track, we believe that the approval process for these products would be facilitated. Based on reports by our affected members, it seems that informal structures have already evolved within the EPA along the lines we are proposing. These informal arrangements have, however, proven inadequate to resolve the problems faced by the antimicrobial/disinfectant

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industry. Some increased degree of formalization appears to be required in order to institute a more efficient and equitable regulatory process for antimicrobial and disinfectant cleaning products.

It seems to us that the establishment of a separate antimicrobial regulatory track would benefit the EPA as well as industry by clarifying standards and establishing an effective division of labor in the FIFRA regulatory approval process.

SDA realizes the enormous task currently being undertaken by EPA in the re-registration of pesticides. We also recognize that the Agency operates, as do all human enterprises, with finite resources. However, the Agency also has a responsibility to see that all its various regulated communities, communities whose ability to conduct business depend on the Agency, receive equitable allocations of regulatory resources. While priorities may need to be assigned, that assignment ought not to unduly encumber the ability of other Agency-dependent, regulated industries to conduct business.

The "Food Quality Protection Act of 1993," H.R. 1627, deals with extremely important issues. My purpose in being here today is to urge you not to lose sight of other FIFRA related matters which, while perhaps more mundane by comparison, are deserving of your attention in the development of FIFRA related legislation.

While I wish that I could offer you a comprehensive solution to the issues of our concern, I cannot do so today. I am pleased to tell you, however, that the SDA is currently working to develop a more concrete proposal for your consideration along with allied associations. We are hopeful that our proposal will be available in the very near future.

Mister Chairman and members of the Committee. this concludes my formal remarks. The SDA appreciates the opportunity to be here today and I would be pleased to answer any questions you might have at this time. Thank you.

TESTIMONY OF RALPH ENGEL
PRESIDENT
CHEMICAL SPECIALTIES MANUFACTURERS ASSOCIATION
SUBCOMMITTEE ON DEPARTMENT OPERATIONS & NUTRITION
UNITED STATES HOUSE OF REPRESENTATIVES
AUGUST 2, 1993

Good afternoon Mr. Chairman and members of the Subcommittee, my name is Ralph Engel. I am President of the Chemical Specialties Manufacturers Association (CSMA). CSMA has a membership of some 440 companies engaged in the manufacture, formulation, distribution and sale of pesticides, antimicrobial products, automotive products, detergents and cleaning compounds and polishes and floor finishes for household, institutional and industrial use. A significant number of these products have pesticidal claims and are therefore subject to EPA jurisdiction pursuant to the requirements of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA).

Specifically, CSMA represents the nonagricultural pesticide industry, including disinfectants and sanitizers, alone or together with cleaning compounds, home, lawn and garden pesticides and a wide variety of pesticides for home, industrial and institutional use.

The Food Quality Protection Act (H.R. 1627)

While the vast majority of CSMA members do not produce products to be used on food, feed or fiber crops, we do recognize the need for Congress to enact comprehensive food safety legislation which both resolves the Delaney

paradox and appropriately streamlines FIFRA's cancellation and suspension procedures. The Lehman/Bliley legislation (H.R. 1627) is clearly the most serious and balanced effort to accomplish those goals under consideration in the 103rd Congress. That is why it has attracted more than 100 bipartisan cosponsors; CSMA supports the Lehman/Bliley legislation.

Delaney Clause

The Ninth Circuit Court of Appeals decision in Les V. Reilly 968 F.2d 985 (Ninth Cir. 1992) has reemphasized the need for Congress to enact a "negligible risk" standard for establishing legal pesticide residues in food. A zero-risk standard, as required by the Les decision, would significantly limit the availability of pesticidal products which offer substantial benefits to society without threatening the public health.

Overly restrictive definitions of "negligible risk," as proposed by Representative Waxman (H.R. 872) are equally troublesome. CSMA supports a "negligible risk" standard consistent with present risk ranges (1×10^{-5} to 1×10^{-6}) used by EPA, FDA and other Federal agencies. The risk assessment process used by EPA in setting tolerances should not be prescribed in statute, as is done in H.R. 872; EPA should instead be provided with appropriate scientific flexibility and discretion, as is contemplated by the Lehman/Bliley narrative "negligible risk" standard.

Cancellation and Suspension

Over the past few years, EPA has expressed concern over what it considers to be the cumbersome and time-consuming process required to cancel or

suspend a registration. CSMA understands the Agency's concern and believes it should be provided the tools to promptly address pesticides which pose an unreasonable adverse effect to human health or the environment as established by sound science. Those reforms should be balanced by the preservation of appropriate due process protections as are proposed in H.R. 1627. Our goal should be to ensure an adequate chance for rebuttal by the registrants as well as a proper forum for consideration of all relevant factors for cancellation or suspension of a pesticide. CSMA will continue to objectively look at any reasonable proposal offered by EPA and others concerning this issue but remains committed to maintaining appropriate procedural safeguards in the cancellation and suspension process.

The Registration Program

Mr. Chairman, your decision to focus your first FIFRA hearings two months ago on the problems plaguing the EPA pesticide registration program has served to bring to the forefront the cumbersome and anticompetitive registration process and the widespread dissatisfaction with the program's performance. Representatives of the agricultural and non-agricultural chemical, biotechnology, cleaning and antimicrobial industries all expressed serious concerns about the program's ability to meet Congressional mandates for registration of pesticides. The registration process is not working and EPA must be held accountable and be specifically directed to immediately institute procedures to unclog the system.

During the June 8th hearing, you concurred with an idea put forward by the Chemical Specialties Manufacturers Association and supported by others, that

an independent external examination of the Office of Pesticide Programs (OPP) and the entire registration and reregistration program is in order. We urge that such an effort be undertaken promptly and that a report to Congress with specific recommendations for improved program performance be available for review at the start of the 1994 Congressional session.

The consequences of a malfunctioning federal registration system are far reaching. Companies which have made enormous investments in product research and development are stymied by the Agency's inability to make decisions. Moreover, products which are important to the public health and safety are being denied market entry. Increasingly, these problems are taking their toll on an industry with a significant contribution (\$8.26 Billion Annual Sales) to the American economy.

Antimicrobial Pesticides

One of the most compelling illustrations of the problems with the EPA registration system is the fact that it has been seven years since any new antimicrobial active ingredient has been registered.

The fate of antimicrobial products has been caught up in the registration morass because they are included in the definition of pesticides in FIFRA. These products have non-food uses such as disinfectants used in hospitals, institutions, health care facilities and homes; they provide benefits for maintaining the public health. In flood-stricken areas of the Midwest now, insect repellents, disinfectants, and bleach are among the most sought after products.

Changes in FIFRA need to be enacted to address the antimicrobial product area. We believe that antimicrobial pesticides should be distinguished from other pesticides by establishing a separate statutory definition for antimicrobials within FIFRA. Similarly, the establishment of a dedicated EPA function to handle antimicrobial registration applications would accelerate review within the Agency and would permit more precise accountability.

Expedited Review

In the 1988 FIFRA amendments, Congress created an expedited review, so-called fast-track, for registration applications which are identical, or substantially similar, to a currently registered pesticide product. EPA acknowledged on June 8th before this Subcommittee that, five years later, it still faces enormous fast-track backlogs. Further, the Agency has not spent the \$2 million/year specifically earmarked by Congress in the 1991 Farm Bill amendments to eliminate this backlog. Perhaps most disturbing is the Agency's June 8th testimony declaring that it has no intention of attempting to reduce the existing fast-track backlog during FY'93.

CSMA is presently engaged in a coordinated effort to design legislative remedies to correct the present unacceptable EPA registration process. A long list of reports by the General Accounting Office and the Agency's Inspector General now detail the program's poor performance. We are convinced that the need for legislative reform of the registration program is compelling and that such reforms must be included as part of a comprehensive vehicle addressing these issues as well as food safety.

Coordination and Synchronization

The issue of data requirements and uniform standards of review in evaluation of data by EPA and the states continues to be critical for both active ingredient manufacturers and formulators of pesticides in obtaining registrations with EPA and from the various states. CSMA recognizes the need to fill data gaps at both the state and federal level and is not suggesting that the state requirements be necessarily preempted by EPA decision-making. However, CSMA does urge that as part of the registration and reregistration process the states and EPA coordinate and synchronize data requirements so that only one set of data needs to be generated within the same timeframe and that the standards of review used by both EPA and the states for examination and evaluation of new and existing data are the same. The adoption of legislation similar to that introduced by Representative Gunderson in the last Congress, (H.R. 3882) would accomplish this goal.

We appreciate this opportunity to testify today and look forward to working with the members and staff of the Subcommittee on these and other important matters.



AGRICULTURAL RETAILERS ASSOCIATION

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Testimony

of the

Agricultural Retailers Association

before the

House Agricultural Subcommittee on

Department Operations and Nutrition

regarding H.R. 1627

The Food Quality Protection Act of 1993

and other

FIFRA Reauthorization Issues

Presented by

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August 2, 1993

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Agricultural Retailers Association

Testimony regarding

H.R. 1627 and FIFRA Reauthorization

August 2, 1993

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Agricultural Retailers Association
Testimony regarding
H.R. 1627 and FIFRA Reauthorization

August 2, 1993

Introduction

Mr. Chairman and other members of the subcommittee, I would like to thank you for the opportunity to testify today regarding H.R. 1627 and general FIFRA reauthorization issues impacting retail dealers of crop protection chemicals on behalf of the 6000 retail outlet members of the Agricultural Retailers Association or ARA. I am General Manager for Johnston Fertilizer, Robstown, Texas. Johnston Fertilizer services 150 farmers growing cotton, grain sorghum, corn, and ranchers with coastal bermuda grass with liquid fertilizer and crop protection chemicals.

I wish to commend this subcommittee for its efforts to move the food safety issue and FIFRA reauthorization forward. As you will see in my testimony, the U.S. agriculture industry now faces a critical moment in its history. Should we lose the benefits of crop protection chemicals and the ability to register new products because of overly stringent food safety laws, the future of America's abundant and safe food supply will be put in jeopardy.

Part I

H.R. 1627 - Food Quality Protection Act of 1993

"The Agricultural Retailers Association generally supports H.R. 1627 with minor amendments and clarification".

Title I: Cancellation and Suspension.

Even though ARA supports the major provisions set forth under Title I, we do have concerns regarding one specific aspect of the Title. Under Section 102 (b) (1), it states that:

"Notwithstanding any other provision of this Act, the administration may, by use of informal rule making under this subsection, prescribe requirements regarding the composition, packaging, and labeling of a pesticide ---,".

ARA is concerned that the new authority granted to Environmental Protection Agency (EPA) by Section 102 could create major problems for retailers with regard to packaging of pesticides. Because of the advent of refillable pesticide containers, to reduce the use and disposal of nonrefillable pesticide containers, many retail dealers now own containers. Should, through informal rule making, the Administrator decide to change the packaging requirements for one or all containers used with a common active or inert

ingredient, a substantial financial impact could be realized by dealers and farmers who own numerous refillable containers.

As a result of the amendments to FIFRA in 1988 (40 CFR Part 165), standardized packaging will be mandated through container design and performance standards by the EPA. Due to these mandated changes to packaging (container) requirements and the substantial investment made by retail dealers and farmers to purchase new refillable containers meeting the FIFRA 88 requirements, ARA requests that the word package be taken out of Section 102 (b) (1).

ARA is supportive of H.R. 1627 Title I requirements which include consideration of the impacts on the agricultural economy and food prices when cancelling or changing classification or other terms or conditions of registration of a pesticide. It is extremely important that pesticide benefit considerations remain a part of the pesticide registration process.

Title II: Data Collection

ARA is supportive of the collection of pesticide use information. Under Section 201 of Title II, it states that:

"The Secretary of Agriculture shall collect data of Statewide or regional significance on the use of pesticides to control pests and diseases of major crops and crops of dietary significance, including fruits and vegetables. Such data shall be collected by surveys of farmers or from other sources offering statistically reliable data."

ARA suggests that "other sources" be better defined by H.R. 1627 or eliminated so as not to grant either the USDA or EPA the authority to require mandatory recordkeeping and reporting for all pesticide products used. According to the USDA, statistically accurate pesticide use data can be collected through surveys that are as reliable as actual use data at a much cheaper cost than collecting actual pesticide use records.

Under current FIFRA (Sec. 11) and Farm Bill requirements (7CFR Part 110), retail dealers and farmers already keep records on the use of restricted use pesticides (RUPs). ARA requests that this currently burdensome requirement not be expanded needlessly when statistical surveys can provide accurate data.

Under Section 202 (2) of Title I, it states:

"The Administrator and Secretary of Agriculture shall research, develop, and disseminate integrated pest management techniques and other pest control methods that enable producers to reduce or eliminate applications of pesticides which pose a greater than negligible dietary risk to humans, with a special focus on crops critical to a balanced, healthy diet and which are considered as minor crops in terms of acreage produced."

ARA supports this provision but suggests that specific language be incorporated into FIFRA which promotes a greater public/private partnership for actual dissemination of the integrated pest management (IPM) information. USDA data indicates that a great majority of crop production information a producer receives comes from retail crop protection chemical dealers. ARA suggests that the Federal Government can increase the adoption of IPM and reduce the cost of federal programs by exploring ways to enhance the use of private enterprise to assist in the distribution of this information. This issue is further explored later in my testimony.

Title III: Amendments to FFDCA.

ARA supports H.R. 1627's proposed amendments to the Federal, Food, Drug and Cosmetics Act (FFDCA). The changes suggested in this bill are necessary to insure that the continued loss of crop protection chemicals under the provisions of the outdated Delaney Clause does not continue. In addition, the prescribed changes to FFDCA will enable registrants to register new, potentially reduced risk pesticides in the future.

"Congress should not decide specific levels of pesticide residue which are considered acceptable for protection of the food supply based on public policy as prescribed in Representative Henry Waxman's bill H.R. 872. Instead, Congress should pass H.R. 1627 which allows "science" to establish acceptable food safety standards."

Part III

Other FIFRA Issues Not Contained in H.R. 1627

A. PESTICIDE RECORDKEEPING

As mentioned earlier in my testimony, ARA is opposed to the expansion of pesticide recordkeeping and reporting requirements. Even though this is not an issue specifically addressed in H.R. 1627 or any other FIFRA legislation introduced to date, we feel that it is important to express our position on this issue due to the fact that environmental activist groups continue to call for expanded pesticide recordkeeping.

FIFRA already requires recordkeeping for restricted use products by retail dealers. In addition, under the 1990 Farm Bill, agricultural producers are required to keep records of restricted use pesticide applications.

Under the Farm Bill provisions, agricultural producers are required to keep the following information for each application:

1. The brand or product name and the EPA registration number of the pesticide applied.
2. Total amount applied.

3. Location of the application, size of area treated, and crop, commodity, stored product, or site to which the pesticide was applied.
4. The month, day, and year when the RUP application occurred.
5. The name and certification number of the certified applicator who applied or supervised the application of the RUP.

Even though many retail dealers and farmers keep records on all pesticides used, we do not support expanding mandatory recordkeeping to all pesticides for the following reasons:

1. The recently finalized Worker Protection Standard (WPS) requires extensive training, certification, and required knowledge and posting of pesticide applications. Farmers and custom applicators must provide pesticide specific information to workers and handlers and health care personnel on pesticide being applied and handled. These requirements negate any health benefit that could be gained from additional recordkeeping.
2. Collection of records is very expensive, especially in relation to the knowledge gained. USDA data shows that using producer surveys instead of actual pesticide records is much cheaper and is just as accurate as collecting actual records.

B. APPLICATOR CERTIFICATION AND TRAINING

Applicator certification and training is not addressed in H.R. 1627, however, due to expected calls for Legislative expansion of the program, we would like to point out that the EPA has the authority and is using their authority to revise the program. As a result of an EPA proposal (40 CFR Part 171, 55 CFR 46890) to expand the Applicator Certification and Training Program, a final rule is expected later this year.

The expanded Applicator Certification and Training program is expected to do the following:

1. Expands pesticide uses for which certification is required.
2. Establishes private applicator categories which include training of workers by certified applicators.
3. Establishes additional commercial applicator categories and subcategories of certifications which cover non-field use such as pesticide handling at dealer locations.
4. Revises general and specific standards for competency, including elimination of non-reader provision.

5. Establishes various levels of supervision and training requirements for non-certified applicators.
6. Expands commercial applicator recordkeeping to include training provided to non-certified applicators.
7. Establishes more stringent recertification procedures.

C. CROP CONSULTING BY AGRICULTURAL RETAILERS.

Due to the fact that language was incorporated into FIFRA reauthorization legislation (H.R. 3742) last year which would have prohibited agricultural retail dealers from providing crop consulting advice to agricultural producers in certain cases, ARA wants to go on the record as opposing any such legislation that may be considered during current FIFRA reauthorization proceedings. It is important to note that the Agrichemical industry has taken proactive steps to address the potential conflict of interest issue that arises when retail dealers sell products based on pest control advice that they have made to a producer. Following are our reasons for opposing mandatory crop consulting restrictions with regard to retail dealers recommending pesticides.

1. The agrichemical industry has voluntarily adopted the Certified Crop Advisor (CCA) program which was developed by the American Society of Agronomy (ASA). The goal of the CCA program is to certify individuals that will design and recommend pest management and plant nutrition strategies that are both economically and environmentally sound (outline of program attached). The CCA program is now being adopted in numerous states.
2. Providing sound agronomic advice to producer customers is a self-insuring proposition. If a retail dealer provides bad advice to his producer customer, he will lose that customer's business. Retail dealer businesses are located side-by-side with their producer customers. The risk of providing bad advice is the loss of ones' business.
3. Conflict of interest issues are not the status quo. In fact, conflict issues are "very" rare and take care of themselves (see 2). There is no problem in which legislation and millions in taxpayers money is needed to correct.

D. MINOR USE PESTICIDES

ARA would like to express its support of minor use legislation (H.R. 967) introduced by Agriculture Committee Chairman de la Garza and would like to encourage its adoption

as part of a FIFRA reauthorization bill. I cannot begin to express the urgency of passing legislation which will provide relief for producers of commodities that rely on minor use products such as those produced in south Texas.

As we have already seen this year, EPA's revocation of Section 18 exemptions for pesticide products applied to minor use crops have left many producers with no alternative crop protection chemical products. Unless H.R. 967 is put into law and registration procedures are streamlined, pesticide registrants have indicated that we will see an increase in the loss of minor use products.

E. PREEMPTION

The passage of preemption legislation is sorely needed to protect retail crop protection chemical dealers whose marketing area crosses over several legal boundaries. As a result of Supreme Court Case *United States Public Intervenor vs. Mortier*, local governments can now create their own unique set of pesticide laws without any scientific justification.

Today, local ordinances are being created around the country which establish a tremendous burden for retail dealers when trying to comply with the law. For example Johnston Fertilizer has a sales area which includes three counties and six townships. As a result of local preemption, three townships may establish differing posting requirements for application, one county may create its own pesticide recordkeeping rules and then another county may establish pre-notification requirements before a pesticide can be applied. The bottom line is that numerous laws may be enacted which will make it impossible for small businesses such as Johnston Fertilizer to comply with regulations and stay in business.

F. WORKER PROTECTION STANDARD

We believe that this Subcommittee should take a careful look at the recently finalized Worker Protection Standard. From our perspective the standard is the most comprehensive and burdensome regulation ever issued to impact agricultural producers, commercial applicators, and retail dealers. To give you an example of its complexity, the How-to-Comply manual which "summarizes" the regulation is over 150 pages long.

Mr. Chairman, what concerns ARA the most about the recently completed Worker Protection Standard is that Congress never specifically mandated its enactment. The EPA has now taken only a few words in FIFRA and expanded upon them to create the most confusing set of regulations ever issued to impact growers and dealers. On top of this, the tight compliance dates set forth in the final rule are now reeking havoc on product manufacturers who must amend product labels to comply with the standard. The EPA issued guidance so late for amending pesticide labels, it is now impossible for registrants to meet the deadlines which will in turn create major problems for dealers and producers who must comply by April 21, 1994.

Even though ARA and certain members of Congress have called for extending the Worker Protection Standard deadlines, the EPA has remained firm. Inaction by the EPA will create tremendous problems for our industry. ARA requests that this subcommittee conduct some oversight hearings on the Worker Protection Standard in the very near future before it's too late to provide adequate relief to small businesses and producers.

G. PUBLIC/PRIVATE PARTNERSHIP

ARA requests that Congress, adopt as part of FIFRA re-authorization, language which promotes an expanded partnership between the EPA, USDA, and private industry for the dissemination of pesticide use information. Even though data has shown that agricultural producers receive over 80% of their production information from agricultural retail dealers, we do not think that federal or state government agencies and departments are adequately using the potential link-up with private industry to promote the information that it creates. At recent meetings regarding adoption of integrated pest management strategies by agricultural producers, ARA heard many research scientist and government personnel complaints about the lack of adoption of IPM information by producers and difficulties in disseminating this information. ARA would like to suggest that retail dealers be considered a primary source of disseminating IPM and other information to producers rather than as a competitor to the Department of Agriculture's Extension Service.

Considering the federal deficit, ARA believes it is time for Congress to seriously consider using private industry as a primary component in distributing production information. Dealers already have the expertise and resources to get the information out to literally every agricultural producer in the United States. Further, we feel that the use of dealers for dissemination of this information would enhance, not hinder, adoption of IPM and other agricultural practices while saving tax dollars.

H. BIOREMEDIATION RESEARCH

ARA would like to suggest the adoption of FIFRA language which promotes bioremediation of pesticide research. Recent studies indicate that cost effective, user friendly, bioremediation technologies can be developed to deal with pesticide cleanups. The benefits of developing cost effective bioremediation technologies include speeding cleanup so that point and nonpoint source contamination of ground and surface water does not occur.

Currently, the EPA along with ARA have developed a blueprint for increased bioremediation research which is being partially funded through Superfund. However, this research effort is not enough to address the quickly moving remediation initiatives currently being adopted in several states around the country.

The federal government already has the research capability to effectively address this issue through combined USDA, EPA, and Defense Department Initiatives. This subcommittee, through FIFRA reauthorization, can insure that bioremediation of pesticide research is expanded so that contaminated areas are cleaned up in the near future

without bankrupting thousands of small businesses around the country.

I. SUSPENSION AND CANCELLATION

We suggest that Congress amend current pesticide suspension and cancellation procedures in order to allow for the use of existing suspended and cancelled stocks in the channels of trade unless the Administrator decides their continued use is hazardous. Currently, suspension or cancellation of a pesticide may result in millions of pounds of product having to be handled, shipped and eventually disposed of at great expense and exposure to those handling the product.

It is our contention that stopping production and allowing continued use of product in the channels of trade will actually reduce handler and applicator risk as compared to current suspension and cancellation procedures. In addition, the complicated process of recalling pesticides after a suspension or cancellation actually results in products being stored indefinitely such as in the case of Dinoseb because of the high cost of disposal, fear of regulatory repercussions, and a simple lack of understanding among holders of product.

The EPA recently proposed complex regulations to meet the mandated pesticide recall changes placed into law when FIFRA was re-authorized in 1988. It is our suggestion that allowing continued use of suspended and cancelled product in the channels of trade has the following advantages over the recently proposed recall regulations:

1. Continued use reduces risk of exposure to product when compared to recall procedures.
2. Insures the intended use and eventual degradation of the product.
3. Insures that products are not hidden away, eventually contaminating the environment because of improper long term storage or in the worse case, human exposure.
4. Greatly reduces government and private sector cost.

PART III

Update on the Economics of Environmental Regulation.

At no other time in the history of U.S. Agriculture have environmental, worker safety, and transportation regulations had such an impact on our rural communities and businesses. Specifically, new regulations impacting retail dealers of crop protection chemicals and fertilizers have dramatically increased regulatory compliance cost, and in the end, actual agriculture production cost. Unless Congress realizes the impacts of their actions and changes course soon, tremendous negative consequences will result.

ARA estimates indicate that for a "small" retail dealer marketing between \$1 and \$2 million dollars per year of crop protection chemicals and fertilizers regulatory compliance cost will increase from approximately \$25,000 per year in 1990 to \$99,000 by 1997. This represents an unbelievable regulatory compliance cost increase of over 300% in just 7 years (See Attachment 1).

The expected consequences of these regulatory compliance cost increases include:

1. An expected loss of approximately 30% of the retail outlets currently in business.
2. Less competition in providing inputs to our agricultural producers which will result in increased input prices.
3. Loss of rural jobs. Studies have shown that a substantial amount of rural employment in agricultural areas is provided by retail agricultural dealers. (In many cases retail dealers are the largest employer in rural towns.

Congress must help to insure that the impacts of FIFRA and other laws are fully considered before more stringent regulatory requirements are put into place.

Conclusion

Mr. Chairman and Members of the subcommittee, I would like to thank you for allowing me to testify on behalf of the Agricultural Retailers Association. I would be happy to answer any questions at this time.

(Attachments follow:)

Certified Crop Adviser Program

Summary

The American Registry of Certified Professionals in Agronomy, Crops, and Soils (ARCPACS) program of the American Society of Agronomy (ASA) is creating a certification category for crop advisers as a result of action taken on 1 November 1991 by the ASA Board of Directors. ARCPACS has been certifying agronomy, crop, and soil professionals for over 15 years using a BS degree and 5 years of work experience as the base standard.

The Certified Crop Adviser (CCA) program will not require a college degree, and is being developed for those who recommend crop management strategies to farmers and who may or may not be involved in selling products. The CCA program is being developed by representatives from agribusiness, ag consulting, government agencies, and universities. The intent of the program is to set base standards for certifying crop advisers. The program will operate as a part of ARCPACS, which is a membership service of ASA.

The CCA program has a four-year standard of post-high school experience working with growers, allowing for college education to substitute for up to two years of the work experience requirement. An examination will be used as the basis for the certification of crop advisers. The exam will cover the knowledge-skill areas of crop production practices, including soil fertility, crop production, soil and water management, integrated pest management, and regulatory aspects involved in these areas. All applicants for certification will take the CCA exam. Once certified, CCA registrants must participate in a continuing education program, currently being designed.

All applicants certified under the CCA program will subscribe to a Code of Ethics. An Ethics Review Committee is reviewing the current ARCPACS Code of Ethics for its applicability.

Another unique feature of the CCA program is that the certification boards will be developed in each state that participates in the program. Each state board will include a representative from the state environmental agency, extension, and agribusiness, plus three to four at-large members. The state boards will be responsible for developing exam questions that address specific state problems and regulations, safeguarding eligibility requirements, and exam administration.

Aspects that continue to be discussed by the Steering Committee, in the process of implementing the CCA program, involve potential public perception of the program and conflicts of interest associated with disclosure of information, as appropriate, on sale of products, equipment, or services by the crop adviser.

The CCA program is a departure from current ARCPACS certification in that it is based on a four-year post-high school experience requirement, rather than five-year post-college experience, and on passing a comprehensive examination. The program is designed to identify the persons capable of working with growers and producers to develop and implement environmentally and economically sound nutrient and pest management strategies.

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COST FOR AVERAGE DEALER TO MAINTAIN REGULATORY COMPLIANCE

<u>Regulation</u>	<u>Date Effective</u>	<u>Avg. Cost</u>
FIFRA 88 Storage and Disposal (Requires dealers to build dikes, runse pads, fire proof warehouses, etc.)	1994	\$175K
Pesticide Record Keeping (Requires dealers to keep detailed records of pesticides sold and applied. The 1990 Farm Bill increases this requirement)	Present*	7.5K
Certification and Training (Requires dealers and employees to obtain training in various areas of pesticide application.)	Present*	3.5K
Other FIFRA Regulations (Special state laws and EPA requirements)	Present*	6.5K
Farm Worker Protection (Requires dealers to train applicators)	Present*	10K
SARA Title III Community Right-to-Know (Requires dealer reporting of chemicals on-site)	Present*	2K
OSHA Regulations (Requires training of employees and safety equipment)	Present*	5K
DOT Hazardous Materials Regulations (Requires 24 hour hotline, manifest, placarding of hazardous materials being shipped)	Present*	6.5K
HAZMAT Training	1993	2K
Commercial Drivers License (Requires drivers to obtain CDL, Drug Testing)	Present*	7.5K
Storm Water Permitting (Requires dealers to hire consultants to perform engineering and testing of storm water run-off at individual facilities)	Present*	3.5K
Clean Air Act Permitting & Planning	1994*	17.5K
Effluent Guidelines (Requires dealers to build pesticide wastewater treatment system)	1995*	3.5K
Pesticide Waste Removal (Required under CWA, CERCLA, and RCRA)	Present*	3.5K
Pesticide Fees (per year) (State fee for licensing and environmental programs)	Present*	1.5K
Endangered Species Act (Requires reduction or elimination of pesticide application in some areas)	1994*	Unknown
Pesticide Illness Reporting (Requires dealers to report illness related to pesticide exposure in certain states)	Present*	Unknown
Groundwater Protection (Requires dealers to reduce or eliminate pesticide and fertilizer application in some areas under CWA, special USDA programs and the 1990 Farm Bill.)	Present*	5K

AVERAGE COST = \$99,000

Note: [FIFRA 88 cost amortized over 10 years]

* Does not take into consideration impact of Clinton Administration Budget.

Testimony of
Thomas C. Diederich
on Behalf of The
National Pest Control Association

Mr. Chairman and members of the Subcommittee, thank you for allowing me to testify today. We appreciate the opportunity to share with you the views of the pest control industry .

My name is Tom Diederich. I am the Vice President, Government Relations for Orkin Pest Control and Lawn Care, which is headquartered in Atlanta, Georgia. I am also Chairman of the National Pest Control Association's Government Affairs Committee and a member of the Board of Directors of the Professional Lawn Care Association of America.

I am testifying today on behalf of the National Pest Control Association, the national trade association which represents approximately 10,000 professional pest control companies who are engaged in the business of providing structural, institutional and industrial pest control services. These services are rendered primarily indoors to homes, restaurants, hospitals, food processing plants, offices, schools and other public buildings to control pests such as ants, cockroaches, termites, rats, mice, and fleas, which pose a threat to the public's health and property. I am accompanied by Bob Rosenberg, NPCA's Director of Government Affairs.

We applaud the Subcommittee's effort to deal with the important food safety questions which H.R. 1627 addresses. But there are other issues not presently in H.R. 1627 which vitally affect the pest control industry which we believe should be addressed in any amendments to the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). I will confine my remarks to those issues.

I. Once and for all, Congress needs to reaffirm the strong partnership between the state and federal governments.

In June of 1991, the United States Supreme Court overturned the long-standing belief that FIFRA preempted the regulation of pesticides by local units of government or, in other words, the court paved a path to regulatory chaos by permitting the 83,000 local units of government in the United States to each adopt its own set of confusing, contradictory and overlapping regulations. This decision is a potential disaster for pest control companies, the consumers who want and need their services and the individuals charged with regulating this activity.

Companies in the pest control, lawn care, tree care and other industries which may apply pesticides in non-agricultural settings vary in size from large companies, like mine, to very small companies, the proverbial mom and pop operations. In

fact, the overwhelming majority of companies represented by NPCA are small businesses, each employing a small handful of people. As you know, small business is the engine driving our nation's economy.

Big or small, however, we have one thing in common. Unlike many other businesses which may operate from a stationary facility in a single community, pest control companies, even very small ones, typically provide service to customers in dozens or hundreds of communities. If each of those communities adopted its own licensing, training, testing, certification, insurance and sign posting requirements the result would be an unmanageable regulatory patchwork. Worse yet, if each community required permits prior to some treatments, outlawed certain products or prescribed different times of day during which applications can be made, the consequences for my industry and the American public would be catastrophic. Costs will go up, our ability to respond to pest problems which pose a threat to public health will be constrained and ironically, more pesticides will be applied by untrained and unregulated do-it-yourselfers, resulting in a greater misuse of pesticides.

I do not wish to give this Subcommittee the mistaken impression that we oppose the regulation of our industry. To the contrary, we vigorously support responsible regulation of our industry by the state and federal governments which have the ability and technical expertise to competently handle this important task. A careful

reading of the legislative history of this issue should draw you to the conclusion that this clearly was the intention of those who originally drafted the law. To accomplish this, we urge this Subcommittee to adopt an amendment to FIFRA, like last year's H.R. 3850 which had over 100 cosponsors, to restore the traditional effective, strong regulatory partnership between the state and federal governments.

II. Congress needs to enact tougher certification and training standards for commercial pesticide applicators

The second issue we believe Congress must address as it moves to amend FIFRA is to toughen the federal standards for certification and training of commercial pesticide applicators. We believe that proper and appropriate education and training are the cornerstone of an effective regulatory program designed to protect the public and minimize the misuse of pesticides. We urge this Subcommittee to adopt tougher standards.

Under current federal law, only applicators of restricted use pesticides are required to be certified. However, if a person applies a restricted use product under the direct supervision of a certified applicator, that person is not required to have any training. Furthermore, in-house pesticide applicators such as janitors, custodians, groundskeepers and building managers are not subject to any federal requirements

at all, unless they apply restricted use products. In most cases, these do-it-yourselfers are applying products which contain the same active ingredients as the products used by licensed professional pest control companies.

We believe these minimum federal standards are woefully inadequate and need to be upgraded. Many states, including my own, have adopted much tougher certification and training requirements. We think it is time for the federal government to also adopt more comprehensive regulations.

Specifically, we believe that commercial applicators of any pesticide should be subject to federal training standards and the definition of commercial applicators should be broadened to include in-house personnel who apply pesticides to schools, hospitals, apartments, offices and other buildings frequented by the public, though we support exempting individuals whose jobs require the use of anti-microbials or the occasional application of pesticides. We further believe that persons operating under the direct supervision of a commercial applicator should undergo mandatory verifiable training and be registered by state pesticide regulatory agencies.

Bills were introduced in each of the last two Congresses which would have achieved these goals. Senator Lugar's "Pesticide Safety Improvement Act of 1990" in the 101st Congress (S. 2490) and Mr. Rose's "Pesticide Safety Improvement Act of 1991" (H.R. 3742) in the 102nd Congress both contained language which would

have significantly improved the certification and training provisions of FIFRA. In fact, this Subcommittee approved the language when it marked-up H.R. 3742 last year. When this Subcommittee considers FIFRA legislation, we urge you to again adopt language which rectifies this glaring deficit in the federal pesticide regulatory program.

III. Congress needs to take steps to protect industry from the loss of products that protect the American public from disease carrying pests

When Congress last amended FIFRA in 1988, it required the Environmental Protection Agency to reregister all pesticides that were originally registered prior to 1984, including pesticides that are used for the protection of public health. The costs of reregistering pesticides used in institutional and public health pest management programs can be very high and the volume of sales very low. In many instances, it simply is not economically viable to reregister a "minor-use" public health pesticide. We are concerned that this already has and will further result in the loss of some of the important tools which our industry uses to combat pests which pose a threat to public health.

Earlier this year, Mr. Dooley and other members of this Subcommittee cosponsored H.R. 1867, the "Public Health Pesticides Protection Act of 1993", which ensures that products vital to the protection of public health are not lost simply due to the expense of their being reregistered. We support H.R. 1867 and urge you to include it's provisions in any FIFRA legislation adopted by this Subcommittee.

Conclusion

Mr. Chairman and members of the Subcommittee, we thank you for the opportunity to present testimony on these important issues. On behalf of our industry, we urge you to include them in any revisions you make to FIFRA.

NATIONAL FOOD PROCESSORS ASSOCIATION

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TESTIMONY OF JOHN AGUIRRE

U.S. HOUSE OF REPRESENTATIVES

COMMITTEE ON GOVERNMENT OPERATIONS,
THE SUBCOMMITTEE ON HUMAN RESOURCES
AND
INTERGOVERNMENTAL AFFAIRS

July 27, 1993

Mr. Chairman, my name is John Aguirre and I am the Director of Federal Government Affairs for the National Food Processors Association (NFPA).

NFPA is a scientifically and technically based association representing some 500 food companies, including most of the major processors in the United States. Our members manufacture the nation's processed-packaged fruits and vegetables, meat and poultry, seafood, juices and drinks and specialty products.

Our mission is to serve the U. S. food industry and American consumers by helping to assure the safety and wholesomeness of the food supply.

In my testimony today, I will describe the relationship of food processors to growers and the use of pesticides, and efforts by the food processing industry to limit pesticide use and residues in foods. Also, I will comment on questions of policy concerning pesticide use and the importance of pesticides to the economical production of food.

Let me first indicate that NFPA has developed a substantial data base on pesticide residues. This data base contains more than 150,000 food samples and is growing. Despite the capability to measure in parts per million and even parts per billion, we typically do not detect pesticide residues in our testing. When we do find them, residues are at extremely low levels and well below the safe tolerance levels set by the Environmental Protection Agency (EPA).

Federal and state pesticide residue monitoring programs similarly find no or very low pesticide residues in processed foods.

In 1991, the FDA in cooperation with the U.S. Department of Agriculture performed over 5,500 pesticide residue analyses on a

variety of commodities and food products, including 2,304 samples of baby foods. In the baby food samples, 94% of the samples were found to have no detectable pesticide residues. The remaining 138 occurrences were found to contain residues at trace levels, far below tolerance. The survey results also showed that residues of the pesticide aldicarb, a chemical mentioned in the recently released National Research Council report on infants and children, were infrequently detected on bananas and citrus fruits: 8% of 176 samples showed trace levels at 0.19 parts per million.

FDA's pesticide residue monitoring program for FY 1991 analyzed 19,082 samples. In over half of the fruits sampled no pesticide residues were detected and for 68% of the vegetables sampled there were no detectable pesticide residues. Federal, state and private sector pesticide residue monitoring activities confirm that processed foods typically do not contain detectable levels of pesticide residues and when detected, residues are nearly always well below EPA established tolerance levels.

These data indicate that the nation's pesticide regulatory programs are remarkably effective at assuring the safety and soundness of our food supply with respect to pesticide residues. FDA's surveillance samples for domestically produced commodities found that less than 1% of the samples had over-tolerance residues and in the category of imported commodities no violative residues were found in 98% sampled. A violation rate of only 1 to 2% is remarkable for almost any regulated activity, but certainly when considering the size and complexity of our food economy.

Food processors can share in the credit for the uniformly high rate of nondetectable or low levels of pesticide residues in the food supply. Pesticide residue control must begin before food is processed. The focal point of pesticide residue reduction is at the point of application, in the farm field. Pesticide residue analysis requires considerable effort and is expensive, costing between \$100 to \$1,000 per sample, so food processors would rather focus on managing the use of pesticides in the field to ensure that residue levels in processed foods conform to standards.

Fortunately, the physical processes involved in the manufacture of food nearly always result in the reduction of already low pesticide residues on raw agricultural commodities. NFPA staff researched the effects of processing operations on pesticide residues, examining the way in which product peeling, washing, blanching and processing affect residue levels. We know that the amount of removal is influenced by which chemical is used, the crop it is utilized for, and the way in which the commodity is processed. We have documented reductions in residues ranging from 66% to 99% as a result of processing

operations. I have included with my testimony a copy of a study by our Ed Elkins on the effects of processing on residues.

While food processors have confidence in our nation's regulatory institutions and believe that pesticide residues in food pose no significant dietary risk to humans, we nonetheless prefer to minimize or eliminate, where feasible, these pesticide residues. Processors must meet the dual goals of providing consumers a uniformly consistent, high quality, low cost food product while also responding to public concerns over risks from pesticide residues and concerns about the environment. The competing pressures are intense: consumers expect good tasting foods devoid of weeds, bugs or bug parts, and disease damage; farmers need pesticide chemicals to maintain an economically viable operation; and consumers would prefer no pesticide residues.

Because of these competing pressures many food processors seek to manage the type and quantity of pesticide residues in their processed commodities by actively participating in the pest management decisions made by growers. In the grower/food processor relationship both the food processor and the grower desire a quality product with minimal pesticide residue levels. Both the grower and processor incur a business risk in marketing products with detectable pesticide residue levels, despite evidence for their safety. For growers trying to sell commodities to the open market, a pesticide related food scare could result in a substantial, potentially economically threatening, devaluation of the grower's commodity. The Alar/apples scare is ample evidence of this risk. Often, food processors compound this marketing risk for farmers because processors are extremely risk averse and will refuse to accept commodities with potentially controversial pesticide residues. Processors face the same marketing risks as growers, and many food processors will reject commodities with residues of pesticides subject to EPA regulatory review for human health risks. Processors cannot afford to have their inventories of raw product or processed goods rendered unmarketable due to adverse publicity and negative public reaction to a pesticide residue.

In an effort to manage these risks to both commodity growers and the processor, many processors stipulate conditions of pesticide use in production contracts for commodities. Processors control pesticide use on contracted crops by: including in the contract a pesticide clause warning against unapproved pesticide applications; distributing to each grower pesticide lists that contain prior-approved chemicals on each crop; requiring that a complete record be kept of every pesticide applied to the crop; verifying that all applications to the crop comply with federal, state, and processor limitations before the crop is accepted at the plant; and, monitoring pesticide residue levels in raw and finished products.

Food processors, large and small, are constantly evaluating the success and effectiveness of their policies on pesticide use. One example is Ocean Spray Cranberries. Ocean Spray made an evaluation of the need for pesticide use on cranberries intended for processing. The company found that many of the blemishes on the cranberry fruit intended for processing have insignificant effect on the quality of the finished cranberry product. Therefore, cranberries which may be slightly damaged with scars or other minor defects are not of concern. This led to reduced pressure on the grower to apply pesticides.

However, it is important to recognize that food processors cannot dismiss entirely the sensory characteristics of the commodities they process. Food processing is not a highly profitable industry, all the more reason that food processors must be able to produce a uniformly consistent, high quality product.

In the eyes of the consumer, appearance is a principal determinant of quality. Tomatoes for example, can suffer sun scald if the plant is attacked by a disease that results in wilting of the tomato leaves. This results in the exposure of the tomato to full sun which can scald the fruit. Sun scald does not alter the taste of the tomato, but does produce inconsistent white streaks throughout the tomato that create an unappetizing appearance for the consumer. For this reason, it is important that the grower and processor prevent sun scald.

Insect damage is another component of quality standards that may have little bearing on the taste or safety of the product, but can produce obvious defects in a food product. Again, consumers will reject foods that have extensive insect damage, even though such damage may not affect taste. However, not all insect damage is harmless. Fruit worm burrowing deep into a fruit, where they feed extensively, will produce considerable fruit worm excrement and expose the fruit to secondary rot organisms. Worm damaged fruits, such as tomatoes, can create high costs for processors as they must station more workers on the sorting areas of the production line to reject worm infested product.

As a rule, a bug in your processed food would be entirely safe to eat--the insect along with the commodity would have both been cooked. However, army worms in tomatoes or stink bugs in peas are not acceptable to the consumer. Farmers sometimes joke that a little bit of protein wouldn't hurt anybody. This is only partly true, since this unwanted protein can adversely affect sales.

Consumers expect a highly appealing, tasty food every time they purchase a food product. The presence of an insect or disease damaged food material in that product can permanently

disrupt a customer's willingness to make future purchases of that brand. In fact, one negative event can influence the purchasing decisions of an entire family.

An example of an insect problem would be corn borers in snap beans. Corn borers do not prefer to lay their eggs on snap beans, but they will do so when there are high numbers of them. Many of the eggs and larvae die, but the surviving larvae will tunnel into the vines of snap beans, where they cause little problem in terms of lost yield. However, based upon experience, one worm in a hundred pounds of pods can generate numerous complaints from consumers that find portions of worm in their product. Analyzing consumer complaints is a valuable means by which to judge the effectiveness of pest control strategies.

Controlling pests does not always require conventional chemical pesticide strategies. However, no simple solutions exist for most food processors or growers to eliminate the use of pesticide chemicals. A variety of strategies and practices can minimize, and in certain cases eliminate, the need to use pesticides. Some of these practices are listed below:

Host Plant Resistance

Disease resistance is an important factor in the selection by processors of specific varieties of crops. The availability of a broad variety of disease resistant varieties of crops has improved opportunities to produce crops earlier and later in a season, and to expand the geographic range of production for certain commodities.

Cultural Controls

Many food processing operations draw commodities from geographic regions with conditions ideally suited to producing a specific commodity. Ideal locations are characterized by high productivity and low pest pressures, thus lower pesticide use. Also, production on contracted land affords the grower greater flexibility in crop rotations, which can disrupt pest life cycles and minimize the need for pesticide use. At the processing plant, controls can be established that alleviate pest problems and complement pest control strategies in the field (i.e., use of air cleaners to remove stinkbugs from peas).

Monitoring

Scouting of fields by pest managers on a regular basis provides information on pest life cycles, distribution, and damage that permits greater rationalization and effectiveness of pesticide use. Monitoring of pests through trapping techniques can also define when pest populations reach economically meaningful levels, allowing growers to avoid applying pesticides prematurely and unnecessarily.

Modeling

Conceptual models of pest life cycles aid in targeting (and limiting) pesticide applications to the most effective time frames. For example, a predictive model has been developed for white mold in green beans. This model forecasts white mold infection and suggests when prophylactic sprays are needed. Similarly, a model developed for peas has been developed that allows a grower to time a pesticide application to the emergence of the pea aphid into its winged stage of life.

Biological Controls

Pest control strategies that consider preserving predator or parasite populations, so-called beneficials, to control target pests mean that nonchemical pest controls can complement chemical control strategies. Also, the direct introduction of these beneficials can sometimes supplant chemical pesticide applications. The use of microbial controls for pea and bean root rot may replace the need to treat seeds with fungicides prior to planting.

The food processing industry is actively looking for ways to reduce the reliance upon pesticide chemicals. From a cost perspective and in response to consumer perceptions, reducing pesticide use can make good sense. However, the agricultural economy of the country is extremely complicated and the success and failure of various systems of agricultural production is characterized by geography, climate, and the presence or absence of pests. The conditions and factors that define the successful production of Georgia peaches may have little meaning to the producer of California peaches. Apple production in Washington or Idaho is a distinctly different enterprise than apple production in Virginia or Pennsylvania.

For these reasons, Congress and our regulatory institutions must avoid a one size fits all approach to pesticide regulation. Our national pesticide policies must be flexible and sensitive to the very specific local conditions that characterize agricultural production.

Mr. Chairman, I want to examine the concept of reducing pesticide use as national policy. It has been stated in various policy making quarters, and by certain interest groups, that reducing pesticide use is a worthwhile policy goal. The premise is that if Congress, or EPA and other federal agencies could cajole, inspire or mandate farmers to reduce the use of pesticides, then something worthwhile will have been accomplished. Specific numerical goals have been mentioned in the area of 10%, 25% or 50%.

The whole notion of reducing pesticide use as a policy in and of itself is confusing and essentially valueless. If Congress were to mandate tomorrow that national pesticide use should be reduced by 25% in FY 1994, and that mandate were

fulfilled, what would we be accomplished? It is unclear.

Before discussing further my concerns with such policy, let me briefly characterize agricultural pesticide usage in this country. There are approximately 2.1 million farms in the United States, 991 million acres of farm land, with about 289 million under active cultivation. According to 1987 farm census data, 913,000 farms reported using pesticides to control weeds, grasses, and brush, and 554,000 farms reported using pesticides to control insects on hay and other crops. In addition, 270,000 farms reported using pesticides to control crop diseases and nematodes, and as defoliants or for fruit thinning.

The bulk of agricultural pesticide use consists of herbicide applications. The two leading pesticides by volume of use are atrazine and alachlor, both herbicides. For 1992, EPA reported that herbicide applications accounted for a little more than 60% of the total volume of pesticides used in agricultural production. Next came insecticides representing 21% of the total used and the remainder was represented by fungicides, nematocides and other types of pesticides.

If EPA or Congress adopts as policy the goal of reducing pesticide usage, then where should this reduction take place? Should, for example, a 25% reduction be evenly distributed across all categories of pesticides used, or should we focus on the largest category, herbicides? In 1982, 430 million pounds of herbicide active ingredient were applied for agricultural purposes and in 1984 that figure jumped 21% to 545 million pounds of herbicide active ingredient. Were Americans or the environment better off because herbicide use in 1982 was 21% lower than in 1984. Similarly, farmers applied 175 million pounds of insecticide active ingredient in 1991, which was 44% less than the 309 million pounds of insecticide active ingredient applied in 1981. Are Americans and the environment 44% better off?

The regulation of pesticide use must be executed with very specific criteria in mind. Whether the policy goal is to protect human health and the environment, or to enhance the profitability of farmers, our policies should be constructed with these specific objectives in mind.

If there are concerns about groundwater contamination or surface water quality, then those pesticides that tend to leach into groundwater or run into our streams, rivers and lakes should be managed accordingly. Perhaps the solution is reducing pesticide use. But, it could also be the use of buffer strips around fields bordering on streams and rivers, or restricting aerial applications to minimize drift in favor of more targeted applications with a tractor towed spray rig, and geographic or temporal restrictions on pesticide use may be appropriate for

vulnerable watersheds and to minimize run-off during the wettest times of the season.

Likewise, if the use of a pesticide poses an unacceptable risk to birds or endangered species, then our regulatory system should focus on how to minimize that risk.

Since the manufacturer of aldicarb discontinued its use for potatoes, until certain questions regarding residue levels and their health implications were resolved, potato farmers have had to rely upon less effective alternative pesticides and make an additional five or six applications than required when using aldicarb. So, the loss of aldicarb, due to one set of concerns, raises another set of possible concerns associated with higher loading of less effective pesticides into the environment. Was the trade-off in the aldicarb situation beneficial?

If Congress and the EPA embrace a policy of reduced pesticide use, then what happens to the use of sulfur as a fungicide in organic agricultural production systems. Sulfur has to be applied at far higher rates than other synthetic chemical fungicides. In the report by the National Research Council (an arm of the National Academy of Sciences) on alternative agriculture, a California organic grower of grapes reported applying sulfur 7 to 14 times during a growing season, at a rate of 5 to 12 pounds of sulfur per acre, per application. This grower could easily end up applying over 100 pounds of sulfur per acre during a growing season. A conventional grower of grapes could apply new synthetic fungicides at a rate of only ounces per acre, or older fungicides at a rate of a couple of pounds per acre and less frequently than required for sulfur. How does the high rate of sulfur use in organic agriculture square with the policy goal of reduced pesticide use?

More important than reducing pesticide use as a broad goal is the idea that pesticides should not be used unless they are safe. We need a pesticide regulatory system that is responsive to public concerns and can quickly act to limit risks as appropriate. For this reason NFPA supports H.R. 1627, a bill introduced by Representatives Lehman, Bliley, and Rowland. I'm happy to note, Mr. Chairman, that you along with 105 of your colleagues have co-sponsored this bill.

A central element of H.R. 1627 is the proposed reform of the Delaney clause as it applies to the regulation of pesticide residues. The Delaney clause is a highly inflexible provision of law that has prevented EPA from exercising its discretion. The introduction of newer pesticides that may be very slightly carcinogenic, but offer many advantages in terms of lower risks to humans and the environment than other noncarcinogenic chemicals on the market is precluded by the Delaney clause. Modernization of the Delaney clause is the single most important

pesticide policy reform needed today.

H.R. 1627 offers many valuable improvements to our pesticide regulatory system. NFPA's member companies believe pesticides in the food supply represent no significant risk to the health of American consumers. However, there is always room to improve and we believe that the regulatory system can be changed, at minimal cost to consumers, farmers and processors, to better safeguard the food supply from the already low risks posed by pesticides.

When considering pesticide legislation, I urge the members of this subcommittee to continue to have faith in the risk-benefit standard that has long guided our regulatory system. Only in the context of benefits can our regulators make rational decisions about managing pesticide risks. There are enormous benefits associated with the use of pesticides, and clearly there are certain risks. It is incumbent upon all of us--policymakers and those in the agricultural economy--to limit in sensible ways the risks associated with pesticides.

In summary, I want to emphasize that the management of pesticide use and residues in food must be the function of very specific objectives. Broad mandates to reduce the use of pesticides may accomplish little of value, or even be counterproductive to public health and the environment. It is important to recognize that farmers do not like to don chemical suits and hop on their tractors to apply pesticides. It's costly and farmers correctly perceive that many pesticides may present relatively high risks to applicators. Farmers will adopt less chemical intensive pest control strategies provided these strategies are effective, contribute to profits, and recognize the constraints on the farm manager's time.

Our system of agricultural production and food processing has served the American public very well. The debate over pesticide policy is appropriate, as we can--and should--continue to refine and improve the pesticide regulatory process.

(Attachment follows:)

NATIONAL FOOD PROCESSORS ASSOCIATION

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Speech by John Aguirre
Director of Federal Government Affairs

July 20, 1993

Risk Education Seminar
at the
U.S. Chamber of Commerce, Washington D.C.

The Delaney Clause

It is my pleasure to be here today at the U.S. Chamber of Commerce. My name is John Aguirre and I am the Director of Federal Government Affairs for the National Food Processors Association.

I am here to discuss with you a grand and enduring mistake of policy enacted into law by our United States Congress, the Delaney clause. The infamous clause was adopted in 1958 without adequate recognition of its limitations, it has failed to contribute to the protection of public health, threatens to drain resources from important regulatory activities, and may prove incredibly disruptive to the agricultural economy.

The Delaney clause is not just one mistake, but actually appears in three provisions of the Federal Food, Drug, and Cosmetic Act (FFDCA), which is the principal source of legal authority for the Food and Drug Administration (FDA). The first passed and most prominent Delaney provision is contained in the Food Additives Amendment of 1958 to the FFDCA. Other Delaney provisions in the FFDCA were passed later and are similar to the first 1958 version, and these provisions govern color additives and animal drugs. The basic intent of the three Delaney provisions is to prevent human exposure to substances found to induce cancer in man or animals.

The Delaney clause that appears in section 409 of the FFDCA is the most often cited of the three provisions. This clause establishes an explicit, highly inflexible limitation against the approval of additives to food or animal feed found to induce cancer. Food additive regulations are required by FDA for such substances as sweeteners and preservatives, and EPA requires food additive regulations for certain pesticide residues found in processed food. The Delaney clause specifically states,

"That no additive shall be deemed to be safe if it is found to induce cancer when ingested by man or animal, or if it is found, after tests which are appropriate for the evaluation of the safety of food additives, to induce cancer in man or animal. . ."

During Congressional consideration of the Delaney clause, early drafts were even more severe than the language which appears in law today. Originally Congressman Jim Delaney of New York proposed that any food additive found to induce cancer be prohibited: the proposed language did not consider that cancer could be induced through inappropriate test procedures. The repeated injection of a substance into a lab animal, for example, may induce cancer that would not be seen through some means of oral exposure more nearly approximating the human experience. After Administration officials objected, noting that many substances including foods such as vegetable oils, sugar or common beverages could be prohibited, Congressman Delaney agreed to compromise language predicated on the application of the anti-cancer clause to food additives on the basis of "... tests which are appropriate for the evaluation of the safety of food additives. . . ." And, that appeared to be the only explicit concession to regulatory flexibility and scientific advances.

In reviewing the legislative history of the Delaney clause there is no reason to believe that Congress recognized the capacity that existed for the technological advances of the three and half decades since 1958, or the implications of such advances. Thus, in 1958 Congress gave birth to a provision which today offers no discernible benefit to society and has been the source of disruption to the operations of FDA and EPA.

A famous example of a food additive to run afoul of the Delaney clause is the sweetener Cyclamate. In 1969 the FDA took action to prohibit the use of the sweetener because of evidence of carcinogenicity in animals. After two decades of regulatory review and legal battles the manufacturer has not been granted approval for cyclamate, despite ample evidence indicating that the sweetener is not carcinogenic. FDA appears reluctant--to state it mildly--to reverse its original decision on cyclamate.

Saccharin would have met a similar fate had Congress not intervened to suspend FDA action against this sweetener. And, saccharin remains the only example of Congress intervening to prevent FDA from banning a specific food additive.

Many bills have been introduced to reform the Delaney clause both for food additives generally, or for pesticides specifically. However, the most vigorous and complete efforts to lessen the severity of the Delaney clause have been through the administrative process. Both FDA and EPA have attempted to interpret the Delaney zero risk standard as permitting negligible levels of risk: risk so small and insignificant as not to merit the invocation of the clause.

In 1986 the FDA approved the listing of the dye and color Orange No. 17 for use under a de minimis interpretation of the color additive Delaney clause. Given the inflexible and extreme mandate of the clause, FDA determined that the extremely low levels of cancer risk presented by Orange No. 17 could be dismissed as negligible: the best conservative estimated risk for Orange No. 17, based on an analysis of rat livers, was calculated as 1 in 10 sextillion, and the upper bound risk (worst case estimate) was calculated to be 1 in 4.8 billion. Given the fact that humans face a 1 and 3, to 1 and 4

lifetime chance of developing cancer, the FDA thought these added risks to be so trifling--in effect zero in human biological terms--that these risk levels would be permissible under a reasonable reading of the Delaney clause. However, reasonableness does not characterize the Delaney clause.

In 1987, a Federal court rendered a decision, in Public Citizen v. Young, that rejected FDA's interpretation of the Delaney clause. The Court, in reflecting upon the intentions of Congress in passing the Delaney language, noted in its decision that the, "... proponents [of the clause] could not have regarded as trivial the social cost of banning those parts of the American diet. . ." threatened by the clause. The court then ventured the thinking that if the anti-cancer provision produced the unexpected or undesirable consequences predicted, the agency should go to Congress for remedy. The court's decision was rendered in 1987 and, of course, today the Delaney clause, written in 1958, continues to hang heavy over our modern food economy.

As you well know, today's detection technology has progressed to an incredible degree of sensitivity. And, the art of chronic toxicology continues to be refined so that more and more substances around us are found to cause cancer-cancer in laboratory animals more accurately. This parallel progress in chemical detection and toxicology have created a nightmarishly inflexible standard out of the Delaney clause.

The Environmental Protection Agency (EPA) published early this year a list of 32 pesticide chemicals, and the crops on which they are used, it deemed vulnerable to prohibition because of the Delaney clause. Like the FDA, the EPA had attempted to read into Delaney a permissible de minimis level of risk. However, this de minimis policy was also struck down in a decision by a Federal court in Les v. Reilly. In the final analysis, the Delaney clause means what it says.

The prospective loss of these 32 pesticides could incapacitate large segments of the agricultural economy. Some of the most adversely affected crops would include rice, sugarcane, apples, grapes, citrus, and hops. Over 70 pesticides have been identified as possibly carcinogenic and many of these may join the list of 32.

A chemical used in rice production, benomyl, is the only chemical control available to control a widespread rice disease in the Delta states where much of our rice is grown. The loss of benomyl would result in a potential annual loss of \$85 million for rice. Another crop, sugarcane would also face severe losses. The chemical atrazine is the single most used herbicide in sugarcane worldwide and no comparable alternative offers the same effective control of weeds at reasonable cost. Apples represent another crop that would take a hard hit if the pesticides listed earlier this year are prohibited. In the Eastern states there are nine diseases that individually affect nearly the entire apple crop in the East. In the mid-Atlantic states, nearly 100% of the apple acreage requires the spraying of fungicides to combat rusts, blights and scabs. In the Western states, where the bulk of our apples are produced, apple scab and powdery mildew affect between 50% to 70% of the crop. The drier conditions in the West mean fewer applications, but during unusually wet weather seasons normally mild pest problems can

turn into severe outbreaks.

Earlier this year EPA took a first step towards implementing the Delaney clause and Les v. Reilly. The agency denied the requests of various State agencies to permit the use of certain pesticide chemicals on an emergency basis within those respective states by farmers for this crop year. The agency estimated that its action could result in losses of \$70 million and this is just the tip of the iceberg. If the Delaney clause is fully and broadly implemented under Les v. Reilly, without significant changes to current EPA policy, then many safe and effective pesticides will be lost at enormous expense to the agricultural economy.

Aside from the immediate and most obvious effect of the loss of a pesticide has on crop yields and economically to farmers, the loss of an important pesticide can have severe repercussions throughout the food economy and to consumers. Pest problems vary by region and season. Many times the judicious use of a pesticide makes it economically viable for farmers to grow crops in certain regions or during certain times of the year that would not be possible without the pesticide. For example high moisture in the fall may limit production of certain fruits and vegetables in the absence of an effective fungicide. Thus, the use of a pesticide and the willingness of farmers to produce later or earlier in the season can permit a food processing plant to more efficiently utilize the plant by scheduling processing of a commodity over a longer period of time--this of course keeps manufacturing costs down, keeps people employed and provides market stability to both farmers and consumers. Frequently, the loss of a pesticide may not appear to have a substantial effect on the price of a commodity when that increased cost is factored into the total production and imports of that commodity over the entire calendar year. But, the effect of the loss could be severe for a particular season and region, so for the fall crop of a commodity, say lettuce or strawberries, prices could skyrocket. We may see an absolute decline in national production of certain commodities under the broad implementation of the Delaney clause, but we can also expect very sharp regional and seasonal dislocations as well.

The benefits of pesticide use are clear and for this reason the Delaney clause is enormously frustrating. Our nation's pesticide regulatory process is founded on the notion of risk-benefit balancing. The risk-benefit standard makes perfect sense for pesticides. Only in the context of benefits can society, or our regulatory agencies, evaluate whether or not a certain level of risk is acceptable. No risk is acceptable without some countervailing benefit. The charge has been made, repeatedly, by environmental and consumer groups that all the benefits of pesticides go to farmers and the risks are assumed by consumers. This is hardly the case. Pesticides are essential to an abundant, high quality food supply, at low cost. However, I do believe that the contentious debate over pesticide use and pesticide residues has been helpful to agriculture and the food industry. It has forced us to better articulate the rationale behind the use of pesticides and to identify their benefits. In our urban society the means of producing our nation's food has become an isolated experience, so we need to explain to the consumer and policymakers the fundamental difficulties of producing food.

Two researchers Borlaug and Doswell broadly described the effects returning the agricultural economy to pre-pesticide technology:

"... [I]f U.S. farmers used the agricultural technology of the 1930s and 1940s to produce the harvest of 1985, they would have to convert 75% of the permanent pasturelands in the United States or 60% of the American forests and woodland areas to cropland. Even this may be an underestimation, since the pasture and forestlands are potentially less productive than the land now planted to crops. This would greatly accelerate soil erosion and destroy wildlife habitats and recreational areas."

So, overwhelming are the benefits of pesticide use, that even Senator Kennedy and Rep. Henry Waxman understand that a zero risk standard is impractical. Both Kennedy and Waxman have introduced legislation that would reform the Delaney clause with respect to pesticides, permitting a certain, albeit extremely low level of risk. There is wide agreement that the Delaney clause is dysfunctional and inappropriate for pesticides, but with what standard do we replace it with. That is where the debate begins.

H.R. 1627, introduced by LBR, a bill supported by a great portion of the agriculture and food industry would replace the Delaney clause with a negligible risk standard that gives EPA the flexibility necessary to accommodate future developments in science. This standard would require the EPA to limit the risk of pesticide residues in the food supply to negligible levels. However, in certain very limited situations the agency would have the authority to exceed the negligible risk level in establishing a tolerance for a pesticide, provided extraordinary benefits so justified it.

The findings and recommendations of the 1987 NAS report on the Delaney Clause served as the framework for H.R. 1627. That report found that the strict application of the Delaney clause to carcinogenic pesticide residues in processed foods offered less public health benefit than the uniform application of a negligible risk standard to all pesticide residues in all foods.

Reforming the Delaney clause as proposed in H.R. 1627 will vastly improve the EPA's ability to reduce the risk from pesticides. The risk profile of a pesticide is potentially very complex. Pesticides may present relatively greater or lesser risks in terms of cancer, or to the immune system, endocrine system, and reproductive organs or to neurological development. For these reasons EPA must not be constrained to some artificial and extreme emphasis on cancer risk. To prohibit the use of a slightly carcinogenic pesticide may result in the use of an alternative pesticide far riskier in other categories. In addition, to human risks there are many environmental risks to consider as well. H.R. 1627 will eliminate the myopic focus on carcinogenicity and permit EPA maximum flexibility to address all important risks.

The Waxman/Kennedy approach does not address these important issues. Their legislation is extremely inflexible, very detailed and permits no consideration of benefits.

The Waxman/Kennedy standard that would replace the Delaney clause would repeat the mistake of Congressman Delaney in 1958 and is arguably worse than the current standard because of its wider application to all pesticides.

NFPA is hopeful that Congress will soon move pesticide legislation. However, in the absence of legislation it is important to recognize that EPA has ample authority under current law to minimize the conflict between pesticides and the Delaney clause. In fact, the EPA has unnecessarily brought pesticides into conflict with the Delaney clause; there appears to be little basis in law for some of its policies which have created this conflict. NFPA along with the United Fresh Fruit and Vegetable Association, and with the support of much of the food industry, petitioned the EPA to reform its pesticide tolerance policies and implement Les v. Reilly in a fashion that minimizes the loss of safe and effective pesticides under the Delaney clause. It's unclear whether the EPA will adopt our petition.

Regardless of the means, the potentially disruptive effects of Les v. Reilly and the Delaney clause must be avoided. No element of our modern society is served by adherence to this woefully out of date and inflexible standard.



WRITTEN TESTIMONY
OF THE
CHEMICAL MANUFACTURERS ASSOCIATION

BEFORE THE
COMMITTEE ON AGRICULTURE
SUBCOMMITTEE ON DEPARTMENT OPERATIONS AND NUTRITION

U.S. HOUSE OF REPRESENTATIVES

ON

THE FEDERAL INSECTICIDE, FUNGICIDE AND RODENTICIDE ACT
AND REGULATION OF INDUSTRIAL BIOCIDES

AUGUST 2, 1993

EXECUTIVE SUMMARY

The Chemical Manufacturers Association (CMA) Biocides Panel appreciates the opportunity to present its comments on Federal Insecticide Fungicide and Rodenticide Act (FIFRA) and pesticide regulations. The Biocides Panel is concerned with regulations, legislation and research that affect producers, formulators, and users of industrial biocides .

Industrial biocides, also known as antimicrobials, are defined as pesticides and are regulated under FIFRA. However, industrial biocides are distinguished from other pesticides in that they are not generally applied to food or food products. They are intended to prevent or mitigate degradation, fouling, deterioration or inefficiency caused by microorganisms in manufactured goods, chemical substances and industrial processes or systems, and on surfaces. Importantly, they do not require tolerances under either Section 408 or 409 of the Federal Food Drug and Cosmetic Act.

The Environmental Protection Agency (EPA) has registered only one new biocide active ingredient in the past seven years, even though many applications have been pending for more than eight years. Simple label changes take as long as 2 years. Given these regulatory delays, research efforts to develop new biocides are in danger of being discontinued.

The current regulatory process for biocides has been plagued by numerous problems, including the following:

- o While EPA has issued regulations (40 CFR Part 158) which specify the data requirements for various uses of pesticides, the Agency often imposes different data requirements upon registrants during the registration process. This causes significant delays in issuing registrations. Registrants are not able to anticipate such "additional" data requirements prior to submission of the registration application.

- o Fees are disproportionate to the profits and the magnitude of data reviewed by EPA. Fees charged by EPA in order to maintain the registration of biocides fail to take into account the low relative profit margins of these products. Fees imposed on the biocides under the same system as for other pesticides results in a much higher relative burden on biocides registrants.
- o Currently, the EPA Registration Division's Antimicrobial Branch has only two product managers while each of the other two registration review branches has four product managers. This is especially of concern to the biocides industry because the Antimicrobial Branch handles about two thirds of all active ingredient registrations and about one-half of all registered formulations. This disproportionate staffing contributes to undue delays in the registration process for biocides. EPA should be required to allocate sufficient resources to the antimicrobial program.
- o Even though Congress mandated specific deadlines and time frames within which EPA is to accomplish the registration of substantially similar or identical pesticide products, EPA has been unable to comply with such deadlines.

INTRODUCTION

The Chemical Manufacturers Association (CMA) is a non-profit trade association whose members represent more than 90 percent of the chemical production capacity in the United States. Within CMA, the Biocides Panel is a Chemical Self-funded Technical Advocacy and Research (CHEMSTAR) Panel comprised of 30 companies that manufacture, process, or formulate biocide active ingredients and/or products. The Panel is concerned with legislation, regulations, and research that uniquely affect biocides producers, formulators, and users.

Industrial biocides are pesticides regulated under the Federal Insecticide Fungicide & Rodenticide Act (FIFRA). Industrial biocides are distinguishable from other pesticides in that they are not generally applied to food or food products. They are intended to prevent or mitigate degradation, fouling, deterioration or inefficiency caused by microbial organisms in manufactured goods, chemical substances and industrial processes or systems, and on surfaces. These pesticides normally are used at extremely low levels, typically in the parts per million range in industrial settings and are not broadcast into the environment. Therefore, there is very low potential for either environmental or human exposure to these products. Importantly, they do not require tolerances under either Section 408 or 409 of the Federal Food, Drug and Cosmetic Act.

Industrial biocides are essential to many industrial processes and consumer products. The most obvious uses are in the medical, personal, and public health areas. They are used to sterilize, disinfect, or sanitize objects and surfaces in a wide variety of settings, including hospitals, nursing homes, medical and dental offices, veterinary offices, public buildings, schools and homes.

In addition to health-related benefits, industrial biocides also provide important economic benefits, including increased product durability, resource and energy conservation, and enhanced industrial productivity. When added at very minute concentrations (perhaps as low as only a few parts per million), biocides provide tremendous benefits to a long list of familiar products: paints, plastics, textiles, concrete additives, detergent solutions, adhesives, leather products, paper, polishes, and many others.

Other uses include preserving metalworking fluids (which bathe metal objects throughout their manufacture); treating wood exposed to the weather and other elements; treating textiles used outdoors (e.g. canvas and cordage); and, treating leathers, suedes and furs, and diesel and jet fuels.

Industrial biocides make possible the process of secondary and tertiary oil recovery, extending the useful life of oil fields. Further, as water resources become increasingly scarce in many areas of the world, industrial biocides are being used to treat waste water, making "gray water" available for selected non-potable uses. Manufacturers rely upon industrial biocides to prevent growths on surfaces of the heat exchangers used in many processes, thus reducing costly energy consumption and equipment shut-down for maintenance.

Although a variety of industrial biocides are currently registered for use, new product development is crucial. Microorganisms, which produce multiple generations within a brief time, are capable of rapidly becoming biocide-resistant. Resistance can be slowed or prevented by alternating products, necessitating a variety of active ingredients effective against a single organism. Further, if resistance does develop, it is essential to have alternative products. Moreover, new products must be developed to further refine traditional uses and to meet new needs.

Antimicrobial pesticides are crucial for a wide range of health, economic and resource conservation purposes. Their continued development and use must not be unduly discouraged. The statutory and regulatory framework for these pesticides should be commensurate with their uses and low potential for exposure, and compatible with new product development and commercialization of these products.

THE CURRENT LEGISLATIVE & REGULATORY SYSTEM IS INADEQUATE

FIFRA grants EPA the authority to regulate industrial biocide pesticides differently from other pesticides. However, EPA has declined to employ this authority. This has resulted in a regulatory framework that is not commensurate with industrial biocidal uses, and low potential for exposure. This regulatory framework has presented the potential to cause irreparable harm to the industrial biocide industry.

EPA has registered only one new industrial biocide active ingredient in the past seven years, even though many applications have been pending for more than eight years. Simple label changes for biocidal products take as long as two years. The regulatory process has discouraged research and development efforts for new biocides. Many companies have discontinued research and development, and many more are considering doing the same.

The current regulatory process for antimicrobial pesticides has been plagued by the following problems, among others:

1. EPA does not apply data requirements as they are defined. In order to obtain registration of a pesticide, a set of data must be submitted to EPA. While EPA has issued regulations (40 CFR Part 158) that specify the data requirements for various uses of pesticides, EPA often imposes different data requirements upon registrants during the registration process. This causes significant delays in the registration process. Registrants are not able to anticipate changing data requirements prior to submission of the registration application. In many instances, the review of the registration application progresses for months or even years before the registrants know that additional data will be required. Data generation then takes months or years. This causes unacceptable delays in the registration process and prevents introduction of needed biocides to the market. Definitive data requirements and specific guidelines for conditional registrations (while supplemental data are being generated) are needed.
2. Fees are disproportionate to the profits and to the magnitude of data reviewed by EPA. Fees charged by EPA in order to maintain the registration of industrial biocides fail to take into account the low relative profit margins of these products. Unlike other pesticides, industrial biocides are produced in relatively low volumes, are used in low concentrations, and are competitively-priced. This leads to relatively low profit margins, more akin to bulk chemicals than to specialty pesticides. Imposing fees on the industrial biocides under the same system as for other pesticides results in a much higher relative burden on industrial biocides registrants. Fees should be structured such that they do not

place an undue burden on the biocides industry. Further, these fees are intended in part to support the costs of regulation. The amount of data that EPA must review for a biocide registration is far less than for most food-use and other types of pesticides. Therefore, the regulatory costs should be proportionately lower. As detailed elsewhere in this statement, the biocides industry simply does not receive what it is paying for — the regulatory process is not functioning effectively for the biocides industry, but fees are being collected.

3. There is a lack of resources dedicated to biocidal products at EPA. Currently, the EPA Registration Division's Antimicrobial Branch has only two product managers while each of the other two registration review Branches has four product managers. This disproportionate allocation occurs despite the fact that the Antimicrobial Branch handles about two thirds of all active ingredient registrations and about half of all registered formulations. Disproportionate staffing contributes to undue delays in the registration process for antimicrobial products. It is ironic that a food-use pesticide which will be widely broadcast into the environment, and consumed by humans, takes less time to register than a low-volume, low-exposure industrial biocide. EPA must be required to allocate sufficient resources to provide an effective antimicrobial program.
4. Even though Congress had mandated specific deadlines and time frames in which EPA is to accomplish the registration of substantially similar or identical pesticide products, EPA has been unable to comply with them. These registrations were recognized by Congress as relatively simple; ones that EPA should be able to approve more easily than others. However, our experience has been that even the simplest registrations are delayed and that Congressional intent has not been realized.

SUGGESTED REMEDIES

After reviewing its concerns with the current regulatory system for industrial biocides, there can only be one conclusion: a major overhaul of the system is needed. The system does not accomplish its intended purpose in that new or improved useful products are not able to reach the market. Even simple label revisions require an inordinate amount of time and effort to accomplish. The Biocides Panel has several suggestions for system improvements.

Many of the current difficulties in the regulatory system may very well be addressed by EPA in its management of the pesticide program. For instance, EPA appears to neglect biocides in favor of agricultural pesticides. While the Biocides Panel supports efficient agricultural pesticide regulation, the Panel does not believe that one group of pesticides should be overlooked to permit the effective regulation of another group. EPA must be held accountable for the lack of attention to the biocides program. The EPA should be required to dedicate sufficient personnel to accomplish the needs of the biocides program, commensurate with the relative number of biocide products and related regulatory activity.

FIFRA Section 25 currently authorizes EPA to administer its pesticide programs in a manner that recognizes the differences among types of pesticides. However, EPA has largely ignored the vast differences between pesticides used in food applications and widely broadcast into the environment and those that are not used in food applications and have low human and environmental exposure, as is the case for most biocide pesticides. Thus, EPA should be required by Congress to account for this lack of implementation of FIFRA, which has created an inefficient regulatory system for biocides.

Although FIFRA currently authorizes EPA to develop regulatory programs tailored to varying types of pesticides, Congress may consider specifically requiring implementation of a regulatory process more suitable to biocides. The Biocides Panel believes that regulation of biocides not used in food applications nor widely broadcast into the environment should be changed such that new active ingredients and new formulations or uses of previously registered active ingredients are registered in a much more expeditious manner. This expedited registration could be accomplished by development of a program in which registration data requirements are promulgated by rule-making and consistently observed. The "moving target" in registration data requirements is probably the most significant reason for the inefficiency of the registration process for industrial biocides.

CONCLUSION

The current regulatory framework for industrial biocides is placing an undue burden on a vital American industry. As a result, domestic research and development of needed new products have been discouraged and may soon be discontinued. EPA needs to redirect resources and to address the regulatory processes which are detailed above. While some adjustments in the regulatory processes may be possible under the current statutory framework, other adjustments may require new legislation. The Biocides Panel at CMA is ready and willing to work with Congress and EPA to develop a new regulatory process that will protect public health and the environment while allowing the biocides industry to continue to develop and provide effective products to the U.S. industrial users and consumers of these essential chemicals.

MINISTRY OF AGRICULTURE AND FISHERIES NEW ZEALAND
TE MANATU AHUWHENUA AHUMOANA AOTEAROA



30 July 1993

SUBMISSION BY NEW ZEALAND TO THE SUBCOMMITTEE HEARING ON THE FOOD QUALITY PROTECTION ACT, 2 AUGUST 1993

The New Zealand Ministry of Agriculture and Fisheries (MAF) and the New Zealand Kiwifruit Marketing Board (NZKMB) would like to make the following submission to the hearing on the Food Quality Protection Act (Lehman bill). We appreciate the opportunity to present our views on this bill to you.

Overall, we support the principles and aims of the Lehman bill, as it allows risk assessment to be based on objective scientific criteria as regards food safety and human health. The Lehman bill allows the Environmental Protection Agency to evaluate pesticides based on the best current scientific methods and taking into account the economic and agricultural benefits of the chemical as well as potential health risks.

The bill would support international harmonisation in pesticide regulatory procedures, thus promoting the work currently being done by organisations such as Codex.

We would also like to make the following specific comments.

We agree with the provisions in the bill allowing the Administrator to revoke a pesticide tolerance for reasons of food safety, providing the revocation is based on scientific evidence.

However we are concerned with the provision that "Requires the Administrator, if she takes certain actions with respect to the pesticide registration, to revoke any tolerance or exemption that allows the presence of the chemical or tolerance."

If this provision is used in circumstances not connected with food safety (e.g applicator hazard), we would be concerned that the revocation of any associated tolerance could be an unjustifiable impediment to trade recognising that there are no food safety issues to be addressed. The bill should therefore allow an opportunity for the tolerance to remain in place for imported products.

The bill prohibits the "...establishment of a tolerance higher than the Administrator determines is adequate to protect the public health." MAF feels that there may be a potential conflict between this provision and the work of Codex in harmonising residue levels internationally. In certain circumstances Codex may have to set a tolerance level higher than some countries, such as the US, deem adequate to protect human health in order to recognise

variations in national "Good Agricultural Practice". The bill would seem to preclude US support for these Codex activities.

We are also concerned that the final wording of the bill does not preclude an importer asking for an import tolerance for a pesticide not used in the US and therefore not registered. The ability of an importer to do this greatly facilitates international trade in products which are not grown extensively in the US, such as kiwifruit.

Thank you for the opportunity to comment on this bill.

A handwritten signature in black ink, appearing to read "R. Ivess". The signature is fluid and cursive, with the first name "R." and the last name "Ivess" clearly distinguishable.

Richard Ivess
Chief Plants Officer

(Attachment follows:)



New Zealand Apple and Pear Marketing Board

**SUBMISSION BY THE NEW ZEALAND APPLE AND PEAR MARKETING BOARD
TO THE HEARING OF THE FOOD QUALITY PROTECTION ACT: MONDAY,
2 AUGUST 1993**

The New Zealand Apple and Pear Marketing Board (NZAPMB) appreciates the opportunity to present its views on the Food Quality Protection Act (Lehman Bill).

The NZAPMB was particularly concerned at the possible implications of revoking any section 409 tolerances and especially the revocation of section 408 tolerances on raw commodities if a strict interpretation of the Delaney clause, as detailed in the Federal Register Vol 58:No. 23, is implemented.

The USA market is significant for New Zealand apples, pears and Asian Pears with exports scheduled at about 27% of the export volume of 2.4 million cartons of fruit. The USA market for processed product (AJC - apple juice concentrate) is also significant taking up to 25% of total New Zealand AJC exports.

New Zealand is a disciplined, responsible user of pesticides and the loss of a tolerance or no tolerance on a raw commodity could mean that the current NZ (\$100 million) trade is threatened.

The NZAPMB believes that the proposed Food Quality Protection Act resolves the issues faced by the New Zealand apple and pear industry and therefore supports the Bill.

The NZAPMB supports the principles and aims of the Lehman Bill.

The NZAPMB also concurs with the comments made in the submission by the New Zealand Ministry of Agriculture and Fisheries.

Dr John R Field-Dodgson
General Manager - Research, Development & Quality

Washington Office

Statement of the
NATIONAL PORK PRODUCERS COUNCIL
Before the
Subcommittee on Department Operations and Nutrition
of the
Committee on Agriculture
U.S. House of Representatives
on
H.R. 1627 -- The Food Quality Protection Act
of 1993
August 2, 1993

Submitted by: Karl Johnson
President
National Pork Producers Council
Mankato, Minnesota

National Headquarters

For Office
Use Only

Mr. Chairman and Members of the Subcommittee:

My name is Karl Johnson and I presently serve as President of the National Pork Producers Council. I am submitting this testimony on behalf of the National Pork Producers Council.

The National Pork Producers Council (NPPC) represents approximately 90,000 pork producers through 45 state affiliates. Our members account for more than 90 percent of this nation's commercial pork production.

NPPC is committed to providing the nation with a safe and affordable food supply using the best means available. The future of American agriculture rests in the maintenance of public confidence in the food that we produce. The judicious use of pesticides is an important part of that process because pesticides are essential for maintaining a high-yield agriculture industry that provides abundant food at low cost to consumers.

Pork producers are concerned that the safety of our food supply will be compromised by overly stringent pesticide registration regulations which cause manufacturers to discontinue the creation of vital pesticides. This is of particular concern in the case of minor use pesticides. Minor use pesticides are uses of pesticides for which the potential profit for a registrant does not justify the cost of registration or re-registration. These pesticides are used on all fruits, vegetables, and nuts, as well as on some field crops. These pesticides also have some livestock uses. Expensive re-registration data requirements are causing registrants to not propose many minor use pesticides be re-registered with the Environmental Protection Agency.

Lack of support by chemical companies for re-registration of minor use pesticides, limited markets, mandatory fees, and liability concerns are resulting in voluntary use deletions or even loss of entire groups of pesticides. Incentives are needed for the agricultural chemical industry to pursue minor crop registration, encourage third-party registration, and give direction to the EPA and the Department of Agriculture for minor crop pesticide programs. These types of incentives are found in H.R. 967, the "De la Garza-Roberts" bill, and they should be incorporated into H.R. 1627, the Food Quality Protection Act.

The language of the Delaney clause, which is found in the Federal Food, Drug, and Cosmetic Act, is detrimental to agriculture because it sets a standard which cannot be reached. The Delaney clause declares that no food additive shall ever be considered safe if it can be found to cause cancer in either humans or animals after the additive has been ingested. The Delaney clause's "zero risk" standard allows for no exceptions to its bright-line test.

The Delaney clause had been realistically applied by the EPA through the use of a negligible risk standard. The EPA's negligible risk standard banned only

those pesticides which posed a greater than negligible risk to human health. The National Academy of Sciences (NAS) agreed with this standard. In 1987 the NAS released a report, "The Delaney Paradox," in which it concluded that a consistently applied negligible risk standard, as opposed to a zero-risk standard, would greatly reduce total dietary exposure to pesticides. Furthermore, a negligible risk standard would permit the EPA to focus on regulating pesticides that pose significant risks to people.

In 1992, however, the U.S. Court of Appeals for the Ninth Circuit in Les v. Reilly ruled that the EPA could no longer implement their negligible risk standard when determining which pesticides are safe. The court mandated that the EPA must use the strictest interpretation of the Delaney clause which is the zero risk standard. The result of this court decision is to put into jeopardy the use of more than 35 safe and reliable pesticides, which will ultimately leave the farmer with less productive fields and the consumer with increased prices for food.

The Delaney clause was enacted at a time when science was not as advanced as it is today. Risk assessment has progressed to the point where scientists can now detect parts per billion and parts per trillion of pesticides in our food, which makes a zero risk standard unachievable and unworkable.

Because science and technology are now so advanced, it is possible that a minute trace of a pesticide could be found in pork which had been fed corn that was previously treated with the pesticide. The risk from such a trace of pesticide residue would be minimal at best, but under the current interpretation of the Delaney clause, that pork would be deemed unsafe for human consumption.

We believe the Delaney clause was never intended to be implemented in the manner in which the Les v. Reilly court ruled. In light of this decision, it is critical that the Delaney clause be adequately dealt with in the reauthorization of the Federal Insecticide, Fungicide, and Rodenticide Act.

H.R. 1627 provides a comprehensive and balanced approach to pesticide-tolerance regulation. H.R. 1627 would create a uniform negligible risk standard for pesticide residues in food. No specific risk level would be included in the definition of negligible risk because science will quickly surpass its current level of risk assessment rendering the definition obsolete. The requirements that the EPA calculate dietary exposure based on the proportion of raw agricultural commodities or processed food actually treated with a pesticide, as well as on the actual residue levels detected in treated commodities and processed food, will help avoid consumer confusion and prevent undue food safety scares.

The EPA would retain authority under H.R. 1627 to establish a tolerance level for a pesticide residue which poses a greater than negligible risk if the EPA determines that countervailing benefits for the pesticide exist. The EPA could consider health, consumer, and nutritional benefits, as well as the

impact of the tolerance level on the availability of a safe, affordable food supply.

The National Pork Producers Council supports the manner in which H.R. 1627 handles the Delaney clause. H.R. 1627 would implement standards which are not only realistic, but also stringent enough to protect our food supply. However, H.R. 1627 does not effectively deal with the problem of minor use pesticides. Therefore, the NPPC would support a modified H.R. 1627 which incorporates the provisions of H.R. 967 that address the problem of minor use pesticides.

We believe that effective regulation of pesticides is necessary to insure the safety and productivity of American agriculture, to provide for safe drinking water, to control disease, and to protect the environment. However, any federal legislation to protect our natural resources should be consistent with the goal of allowing the American farmer to operate efficiently and profitably. We must continue to acknowledge that judicious use of agricultural chemicals makes a positive contribution to both producers and consumers.



TEXAS DEPARTMENT OF AGRICULTURE

RICK PERRY
Commissioner

**STATEMENT BY
COMMISSIONER RICK PERRY
TEXAS DEPARTMENT OF AGRICULTURE**

**HOUSE AGRICULTURE SUBCOMMITTEE ON
DEPARTMENT OPERATIONS AND NUTRITION
U.S. HOUSE OF REPRESENTATIVES
AUGUST 2, 1993**

Mr. Chairman and members of the subcommittee, thank you for this opportunity to submit testimony in support of one of the most important legislative matters facing agriculture and America's food industry, H.R. 1627, the Food Quality Protection Act of 1993.

In light of the public's current concern about food safety, we must recognize the need to revise our antiquated food safety laws as they relate to pesticides, and I applaud the bill's authors and cosponsors and the subcommittee for addressing this vital issue.

We must assure the American public that the food in our kids' lunch boxes and on the family dinner tables is safe. We would all suffer — agricultural producers, processors, retailers and consumers alike — if the public lost confidence in the safety of our food supply.

While scientists generally agree that the actual health risk associated with pesticides in our diet is minimal, the public's perception is that pesticides pose the greatest threat to food safety, even greater than microbial contamination that causes food borne illnesses.

This misperception is a tragedy, because Americans enjoy the world's healthiest, most abundant and least expensive food supply. The lawful and judicious use of pesticides is a major contributor to our enviable dietary lifestyle. Rather than chasing elusive solutions to perceived problems, we need to ensure

Testimony - Commissioner Rick Perry

that agriculture can continue to provide a food supply that is safe from unreasonable risks associated with pesticides.

I believe passage of H.R. 1627 will help guarantee that our consumers continue to enjoy the world's safest food supply, while at the same time instilling greater confidence in the safety of the food we purchase.

Above all else, H.R. 1627 will bring sound scientific practices and methodologies to the forefront of determining the proper use of pesticides in agricultural production without negatively affecting consumer health. It will also provide a healthy dose of stability to agricultural producers who would like to know which safe and effective pesticides they will have at their disposal. Finally, with the implications of the court's decision on *Les v. Reilly* having just begun, this legislation provides for a much needed reform of this nation's food safety law.

By repealing the Delaney clause, with its strict and unreasonable zero-tolerance provisions, and providing for a single negligible risk standard for raw and processed foods, the bill will allow the Environmental Protection Agency to rely on solid scientific information on which to base its decisions regarding tolerance levels and risks associated with pesticides.

It only makes sense to provide the federal government with flexibility to determine what is actually safe for consumers. Technology and science are ever changing. The provisions in this legislation for determining negligible risk afford that needed flexibility.

- Although some people are skeptical of the concept of negligible risk, we must realize that we live with it every day. Even if we banned every man-made chemical, we still would not have a risk-free food supply. We have all but ignored the potential health risks associated with most of the toxic materials found in our food supply. By some standards, naturally occurring toxins amount to 99.99% of all the toxins we consume by weight. As one writer recently stated, our chemical companies are amateurs compared to Mother Nature's own chemical factory.

Science has only tested a handful of the hundreds of naturally occurring plant toxins that are found in the food we consume. But of those tested, most have been identified as carcinogenic. The public is willing to accept the risk of

Testimony - Commissioner Rick Perry

naturally occurring plant toxins in minute quantities which are no different than the minute quantities of manmade chemicals.

I support other provisions of the bill, such as directing the Environmental Protection Agency to consider the benefits of a pesticide when determining tolerance levels. This will allow for the consideration of all consumer interests. Also, cancellation and suspension provisions in the bill are fair to the public and the chemical companies.

As a regulator, I support any new finding based on good science that will help us improve our food industry. H.R. 1627 clearly meets this test.

As a farmer, I am committed to bringing Americans the safest, freshest, highest quality food possible. But I won't tolerate irresponsible misuse of agricultural chemicals, because my kids eat the same food that your kids do. H.R. 1627 will ensure the safety of our food supply.

As a father who loves his children, I will continue to feed my son and daughter a wide variety of foods. While I believe that the benefits of good healthy eating outweigh any minuscule risks of possible pesticide residues in our food, I will encourage the agricultural community to continue to reduce any risks to a level that is as low as is humanly possible. But at the same time, we must allow agriculture to continue its phenomenal job of feeding America and much of the world. Agriculture and government must work together to produce the safest food supply on earth. H.R. 1627 will help to make the system better.

Thank you for opportunity to offer my views on this important legislation. I strongly encourage this subcommittee to move quickly in its consideration of H.R. 1627.

**Testimony of
The Professional Lawn Care Association of America
Before the Subcommittee on Department Operations
and Nutrition Committee on Agriculture
August 2, 1993**

The Professional Lawn Care Association of America (PLCAA) appreciates this invitation to present its views on some of the issues not presently included in H.R. 1627. These issues affect the lawn care industry and should be part of any amendments to the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA).

Organized in 1979, PLCAA is the only national trade association representing approximately 1,000 landscape care companies in the United States and Canada. These companies range in size from the small business (employing as few as one or two persons) to large public corporations and franchise operations. Our members provide services to residential and commercial customers that include fertilization and pest control, as well as mowing, maintenance, irrigation, aeration, seeding, landscaping, and ornamental and small tree care. As the national trade association, PLCAA develops educational programs, recommends industry standards and serves as a national voice for the landscape care industry.

PLCAA members are vitally interested in the content and implementation of many aspects of FIFRA, some of which are not addressed in H.R. 1627. Our testimony will address the following issues:

- (1) Certification and training for pesticide applicators and increased education of homeowner "do-it-yourselfers";
- (2) PLCAA's support of preemption of local regulation of pesticide use under FIFRA.

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Certification and Training for Pesticide Applicators

The proper training of employees is one of the most important factors in providing responsible landscape care services to the public. PLCAA plays its part in providing training for its members and others by sponsoring educational seminars and developing and disseminating training materials for the industry.

PLCAA supports the current certification requirements for pesticide applicators under FIFRA. However, it is our position that the standards do not go far enough. Currently, FIFRA allows the application of restricted-use pesticides by technicians who may or may not be trained, so long as the activity is performed under the direct supervision of certified applicators. FIFRA also permits application of general-use products without any training or supervision by a certified applicator. Finally, FIFRA does not require certification of "in-plant" workers, such as grounds maintenance personnel. Taken together, these omissions leave significant gaps in current law.

With these concerns in mind, PLCAA requests the addition of certification and training requirements for pesticide applicators in H.R. 1627, exactly as proposed in the Pesticide Safety Improvement Act of 1991 (H.R. 3742). If enacted, these additions would raise the standards of our industry by requiring state-approved training for all commercial pesticide applicators regardless of whether the pesticides applied are classified for general or restricted use. In this regard, PLCAA further recommends that the mandated training be provided either by approved instructors from the USDA Extension Service, state-approved consulting firms or industry associations, the state lead agency, or licensed applicator firms.

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Further, PLCAA supports the requirement that "in-plant" personnel and those they supervise receive verifiable state-approved training before applying restricted-use pesticides. PLCAA recommends, however, that this requirement be extended to include the application of any general-use pesticide by any in-plant applicators and not be limited to restricted-use pesticides. The need for training and knowledge to properly apply a pesticide should not be limited to restricted-use pesticides, which in fact represent a very small amount of the products applied.

PLCAA also supports the training requirement for state enforcement personnel. This will ensure that state employees charged with monitoring compliance with federal and state laws and regulations are able to fully understand these enforcement requirements.

Finally, while PLCAA believes that the proposed training and certification requirements are essential to responsible landscape care services, our members are concerned that even with this new program, many of the non-commercial users of pesticides--the homeowner or "do-it-yourselfer"--often apply these products without sufficient information, instruction, or label comprehension. Even EPA's 1990 National Home and Garden Pesticide Use Survey suggests that household pesticides "are not always used as carefully or effectively as they should be." EPA believes this provides "a basis for expanding outreach and education programs on pesticide safety for consumers." According to the National Gardening Survey 1991-1992, 62 percent of all U.S. households, or 58 million households, participated in do-it-yourself lawn care in 1991. Only seven million households employ the services of certified and licensed professional lawn care operators. And since the majority of the products used by professionals and do-it-yourselfers are the same, we

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recommend that Congress consider adoption of a voluntary training program aimed at these users. The program could be coordinated by EPA or the USDA Extension Service and implemented by state agencies in cooperation with the industry or its trade associations.

Preemption of Local Regulation of Pesticide Use

PLCAA believes that any comprehensive pesticide legislation must provide for preemption of local regulation to allow commercial applicators to continue to conduct their business in a responsible and rational manner. It is PLCAA's position that regulation of pesticide use must be maintained at the federal and state levels where the technical expertise is available to render sound scientific judgements.

PLCAA stands ready to assist this subcommittee in developing proactive language toward reasonable and responsible regulation of the landscape care/pesticide user industry.

Thank you for the opportunity to present these comments and recommendations.

103D CONGRESS
1ST SESSION

H. R. 1627

To amend the Federal Insecticide, Fungicide, and Rodenticide Act and the Federal Food, Drug, and Cosmetic Act, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

APRIL 1, 1993

Mr. LEHMAN (for himself, Mr. BLILEY, Mr. ROWLAND, Mr. SMITH of Oregon, Mr. ROBERTS, Mr. PENNY, Mr. ENGLISH of Oklahoma, Mr. HOLDEN, Mr. EMERSON, Mr. KINGSTON, Mr. SARPALIUS, Mr. EWING, Mr. DOOLEY, Mr. JOHNSON of South Dakota, Mr. BARRETT of Nebraska, Mr. BOEHNER, Mr. COMBEST, Mr. DOOLITTLE, Mr. CONDIT, Mr. BISHOP, Mr. GUNDERSON, Mr. POMEROY, Mr. ALLARD, Mr. TOWNS, Mr. COOPER, Mr. HALL of Texas, Mr. McMILLAN, Mr. HASTERT, Mr. UPTON, Mr. PAXON, Mr. KLUG, Mr. FRANKS of Connecticut, Mr. MANTON, Mr. BOUCHER, Mr. CRAPO, Mr. BARTON of Texas, Mr. GILLMOR, Mr. OXLEY, Mr. TAUZIN, and Mr. MOOREHEAD) introduced the following bill; which was referred jointly to the Committees on Agriculture and Energy and Commerce

A BILL

To amend the Federal Insecticide, Fungicide, and Rodenticide Act and the Federal Food, Drug, and Cosmetic Act, and for other purposes.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*
3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the "Food Quality Protec-
5 tion Act of 1993".

TITLE I—CANCELLATION AND SUSPENSION

SEC. 101. REFERENCE.

Whenever in this title an amendment or repeal is expressed in terms of an amendment to, or repeal of, a section or other provision, the reference shall be considered to be made to a section or other provision of the Federal Insecticide, Fungicide, and Rodenticide Act.

SEC. 102. CANCELLATION.

Section 6(b) (7 U.S.C. 136d(b)) is amended to read as follows:

“(b) CANCELLATION AND CHANGE IN CLASSIFICATION OR OTHER TERMS OR CONDITIONS OF REGISTRATION.—

“(1) AUTHORITY.—Notwithstanding any other provision of this Act, the Administrator may, by use of informal rulemaking under this subsection, prescribe requirements regarding the composition, packaging, and labeling of a pesticide (or a group of pesticides containing a common active or inert ingredient), or may classify any such pesticide, or may prohibit the registration or continued registration of any such pesticide for some or all purposes, to the extent necessary to assure that the pesticide, when used in accordance with widespread and commonly

1 recognized practice, does not generally cause unrea-
2 sonable adverse effects on the environment.

3 “(2) BASIS FOR RULE.—

4 “(A) The Administrator may not initiate a
5 rulemaking under this subsection unless the
6 rulemaking is based on a validated test or other
7 significant evidence raising prudent concerns of
8 unreasonable adverse effects to man or to the
9 environment.

10 “(B)(i) The Administrator shall submit to
11 a scientific peer review committee established
12 by the Administrator the validated test or other
13 significant evidence upon which the Adminis-
14 trator proposes to base a rulemaking under
15 paragraph (1).

16 “(ii) The scientific peer review committee
17 shall provide written recommendations to the
18 Administrator as to whether the test or evi-
19 dence reviewed satisfies the criteria under para-
20 graph (1) for initiating a rulemaking under
21 paragraph (1).

22 “(iii) The scientific peer review committee
23 shall consist of employees of or consultants to
24 the Environmental Protection Agency who have
25 not been involved in any previous analysis of

1 the validated test or significant evidence pre-
2 sented to the committee and who are expert in
3 the physical or biological disciplines involved in
4 the proposed rulemaking.

5 “(3) PRENOTICE PROCEDURES.—

6 “(A) The Administrator may not initiate a
7 rulemaking under paragraph (1) until the Ad-
8 ministrator has furnished to the registrant of
9 each affected pesticide a notice that includes a
10 summary of the validated test or other signifi-
11 cant evidence upon which the Administrator
12 proposes to base the rulemaking and the basis
13 for a determination that such test or evidence
14 raises prudent concerns that the pesticide
15 causes unreasonable adverse risks to man or to
16 the environment. A registrant shall have 30
17 days after receipt of a notice provided under
18 this subparagraph to respond to such notice.

19 “(B) At the same time that the Adminis-
20 trator furnishes notice to registrants of the pes-
21 ticide under subparagraph (A), the Adminis-
22 trator shall also furnish such notice to the Sec-
23 retary of Agriculture and the Secretary of
24 Health and Human Services. Upon receipt of
25 such notification, the Secretary of Agriculture,

1 when an agricultural commodity is affected,
2 shall prepare an analysis of the benefit and use
3 data of the pesticide and provide the analysis to
4 the Administrator.

5 “(4) ADVANCE NOTICE TO PUBLIC.—

6 “(A) The Administrator after receiving the
7 recommendation of the peer review committee
8 established under paragraph (2)(B) together
9 with any comments submitted by the Secretary
10 of Agriculture, the Secretary of Health and
11 Human Services, and any registrant shall
12 either—

13 “(i) issue an advance notice of pro-
14 posed rulemaking, or

15 “(ii) issue a notice of a proposed deci-
16 sion not to initiate a rulemaking under
17 paragraph (1).

18 “(B) The Administrator shall publish such
19 notice in the Federal Register and provide a pe-
20 riod of not less than 60 days for comment
21 thereon. The notice shall contain a statement of
22 its basis and purpose, which shall include a
23 summary of—

24 “(i) the factual data on which the no-
25 tice is based,

1 “(ii) the major scientific assumptions
2 underlying the notice, and

3 “(iii) a summary of the notice under
4 paragraph (3) and any significant com-
5 ments received from any registrant, the
6 Secretary of Agriculture, and the Secretary
7 of Health and Human Services.

8 “(C) If the Administrator, after consider-
9 ing any comments received, decides not to issue
10 a notice of proposed rulemaking, the Adminis-
11 trator shall publish in the Federal Register a
12 notice setting forth the decision and its basis.

13 “(5) DOCKET.—For each rulemaking under
14 paragraph (1), the Administrator shall establish a
15 docket. The docket shall include a copy of the notice
16 under paragraph (3), of any notice issued under
17 paragraph (4), of the notice of proposed rulemaking
18 under paragraph (6), of each timely comment filed
19 with the Administrator, of the report of the Sci-
20 entific Advisory Panel under paragraph (8), of a
21 record of each hearing held by the Administrator in
22 connection with the rulemaking, and of the final rule
23 or decision to withdraw the rule. Information in the
24 docket shall be made available to the public consist-
25 ent with the requirements of section 10. No factual

1 material that has not been entered into the docket
2 in a timely manner may be relied upon by the Ad-
3 ministrator in issuing a final rule or in withdrawing
4 a proposed rule or by any person in a judicial review
5 proceeding, except for—

6 “(A) information of which the Adminis-
7 trator may properly take official notice, or

8 “(B) information of which a court may
9 properly take judicial notice.

10 “(6) NOTICE OF PROPOSED RULEMAKING.—

11 “(A) Not less than 60 days after an ad-
12 vance notice of proposed rulemaking, except as
13 provided in paragraph (14), the Administrator
14 may issue a notice of proposed rulemaking. The
15 notice of proposed rulemaking shall include a
16 statement of its basis and purpose, a request
17 for any additional data needed, and a bibliog-
18 raphy of all significant scientific data and stud-
19 ies on which the proposed rule is based. The
20 statement of basis and purpose shall include a
21 summary of—

22 “(i) the factual data on which the pro-
23 posed rule is based,

1 “(ii) the major scientific assumptions,
2 legal interpretations, and policy consider-
3 ations underlying the proposed rule,

4 “(iii) a summary of available risk-ben-
5 efit information, including benefits and use
6 information as provided by the Secretary
7 of Agriculture, and

8 “(iv) the Administrator’s analysis and
9 tentative conclusions regarding the bal-
10 ancing of such risks and benefits.

11 “(B) Registrants of the pesticide and any
12 person who submits comments on the proposed
13 rule shall make a report to the Administrator of
14 all scientific data and studies in such person’s
15 possession concerning the risks and benefits of
16 the pesticide that are the subject of the rule-
17 making and were not included in the bibliog-
18 raphy included in the notice required in sub-
19 paragraph (A). If such person receives addi-
20 tional scientific data or studies pertinent to the
21 rulemaking that were not included in such bibli-
22 ography, the person shall make a report of such
23 scientific data and studies to the Administrator
24 promptly after receipt. If the Administrator re-
25 ceives reports containing additional data con-

cerning risks or benefits, the Administrator shall revise the bibliography to reflect such data and make the revised bibliography available to the public.

“(C) The Administrator shall provide a comment period of not less than 90 days after the publication of the notice of proposed rule-making. During such period any person may submit comments, data, or documentary information on the proposed rule. Promptly upon receipt by the Administrator, all written comments and documentary information on the proposed rule received from any person for inclusion in the docket during the comment period, shall be placed in the docket.

“(D) At the same time that the Administrator publishes notice under subparagraph (A), the Administrator shall provide the Secretary of Agriculture and the Secretary of Health and Human Services with a copy of the proposed rule. Not later than 90 days after the publication of the notice of proposed rulemaking, the Secretary of Agriculture and the Secretary of Health and Human Services may provide comments on such proposed rule. When an agricul-

1 tural commodity is affected, the Secretary of
2 Agriculture shall provide to the Administrator
3 an analysis of the impact of the proposed action
4 on the domestic and global availability and
5 prices of agricultural commodities and retail
6 food prices and any associated societal impacts
7 (including consumer nutrition and health and
8 low-income consumers).

9 “(7) INFORMAL HEARING.—

10 “(A) Any person who has submitted a
11 comment may, not later than 15 days after the
12 close of the comment period, request of the Ad-
13 ministrator an informal hearing on questions of
14 fact pertaining to the proposed rule or com-
15 ments thereon. Upon such request, the Admin-
16 istrator shall schedule an informal hearing not
17 to exceed 20 days duration, and to conduct not
18 later than 60 days after the close of the com-
19 ment period. The Administrator shall announce
20 the time, place, and purpose of the hearing in
21 the Federal Register. The informal hearing
22 shall be limited to addressing questions of fact
23 raised by materials in the docket. A transcript
24 shall be made of any oral presentation, discus-
25 sion, or debate and included in the docket.

1 “(B) The Administrator shall appoint a
2 presiding officer who shall have the authority to
3 administer oaths, regulate the course of the
4 hearing, conduct prehearing conferences, sched-
5 ule presentations, and exclude irrelevant, imma-
6 terial, or unduly repetitious evidence.

7 “(C) The presiding officer shall conduct
8 the informal hearing in a manner that encour-
9 ages discussion and debate on questions of fact
10 regarding the docket. The Administrator shall
11 designate one or more employees of the Envi-
12 ronmental Protection Agency to participate in
13 the hearing. Any person who submitted a com-
14 ment on the proposed rule may participate in
15 the hearing and shall be entitled to present evi-
16 dence and argument to support the partici-
17 pant’s position or rebut a contrary position and
18 may choose to present materials in oral or writ-
19 ten form.

20 “(8) REVIEW BY SCIENTIFIC ADVISORY
21 PANEL.—At the time the Administrator issues a no-
22 tice of proposed rulemaking under paragraph (6),
23 the Administrator shall provide a copy of such notice
24 to the Scientific Advisory Panel established under
25 section 25(d). If any person submits comments

1 under paragraph (6) in opposition to the proposed
2 rule, the Administrator shall request the comments,
3 evaluations, and recommendations of the Panel as to
4 the impact on health and the environment of the
5 proposed rule and on any disputed issues of fact or
6 scientific policy that appear to be of significance in
7 the rulemaking. The Panel may hold a public hear-
8 ing to discuss the proposed rule. The Panel shall
9 provide a report to the Administrator not later than
10 30 days after the close of comment period (or, if a
11 hearing has been requested under paragraph (7), not
12 later than 30 days after the end of such hearing).
13 The Administrator shall allow a reasonable time for
14 written public comment on the Panel's report. A
15 copy of the Panel's report and any comments shall
16 be included in the rulemaking docket.

17 “(9) FINAL ACTION.—After considering all ma-
18 terial in the docket, the Administrator shall publish
19 in the Federal Register either a final rule or a with-
20 drawal of the proposed rule. The Administrator may
21 not prohibit a use of a pesticide if alternative re-
22 quirements will assure that the pesticide, when used
23 in accordance with widespread and commonly recog-
24 nized practice, will not generally cause unreasonable
25 adverse effects on the environment. In taking any

1 final action, the Administrator shall take into ac-
2 count the impact of the action on production and
3 prices of agricultural commodities, retail food prices,
4 and otherwise on agricultural economy. The final
5 rule or withdrawal of the proposal shall be accom-
6 panied by a statement that—

7 “(A) explains the reasons for the action;

8 “(B) responds to any comments made by
9 the Secretary of Agriculture or the Secretary of
10 Health and Human Services, and responds to
11 any report of the Scientific Advisory Panel;

12 “(C) responds to each significant comment
13 contained in the docket; and

14 “(D) in the case of a final rule—

15 “(i) explains the reasons for any
16 major differences between the final rule
17 and the proposed rule;

18 “(ii) describes the impact of the final
19 rule on production and prices of agricul-
20 tural commodities, retail food prices, and
21 otherwise on the agricultural economy; and

22 “(iii) explains any significant dis-
23 agreements the Administrator may have
24 with the comments, evaluations, or rec-
25 ommendations contained in the report

1 under paragraph (8) or the benefits and
2 use information described in paragraph
3 (6)(A)(iii) and analysis in paragraph
4 (6)(D) as it bears on the final rule.

5 A final rule issued under this subsection shall be ef-
6 fective upon the date of its publication in the Fed-
7 eral Register.

8 “(10) MODIFICATION OR CANCELLATION.—

9 “(A) A final rule shall state any require-
10 ments, classifications, or prohibitions imposed
11 by the rule, and shall state that each affected
12 registrant shall have a 30-day period from the
13 date of publication of the rule in the Federal
14 Register to apply for an amendment to the reg-
15 istration to comply with the rule or to request
16 voluntary cancellation of the registration. How-
17 ever, if the rule unconditionally prohibits all
18 uses of a pesticide, the rule may provide that
19 cancellation of the registration of the pesticide
20 is effective upon publication of the rule. The
21 final rule may prohibit or limit distribution or
22 sale by the registrant of the affected pesticide
23 to any other person in any State during such
24 30-day period.

1 “(B) Notwithstanding any other provision
2 of this Act, if an application for an amendment
3 to the registration to make it comply with a
4 rule issued under subparagraph (A) is not sub-
5 mitted within such 30-day period, the Adminis-
6 trator may issue and publish in the Federal
7 Register an order canceling the registration, ef-
8 fective upon the date of publication of the
9 order in the Federal Register.

10 “(11) DENIAL OF APPLICATIONS.—Notwith-
11 standing any other provision of this Act, no applica-
12 tion for initial or amended registration of any pes-
13 ticide under section 3 or 24(c) may be approved if
14 the registration would be inconsistent with a rule in
15 effect under this subsection.

16 “(12) AMENDMENT OF RULE.—A registrant, or
17 other interested person with the concurrence of the
18 registrant, may petition for the amendment or rev-
19 ocation of a rule that has been issued under this
20 subsection. The petition shall state the factual mate-
21 rial and argument that form the basis for the peti-
22 tion. The Administrator shall publish a notice of the
23 petition in the Federal Register and allow a 60-day
24 comment period thereon. Not later than 180 days
25 after publication of the notice, the Administrator

1 shall determine whether to deny the petition or to
2 propose to amend or revoke the rule, and publish the
3 determination and its basis in the Federal Register.
4 In making such a determination, the Administrator
5 shall give due regard to the desirability of finality,
6 to the opportunity that the petitioner had to present
7 the factual material and argument in question in the
8 prior rulemaking proceeding, and to any new evi-
9 dence submitted by the petitioner. If the Adminis-
10 trator proposes to amend or revoke the rule, then
11 the procedures established by paragraph (1) and
12 paragraphs (6) through (9) apply. A denial of a peti-
13 tion shall be judicially reviewable as provided in
14 paragraph (13).

15 “(13) JUDICIAL REVIEW.—A decision not to
16 initiate a rulemaking published under paragraph (4),
17 a final rule or a withdrawal of a proposed rule pub-
18 lished under paragraph (9) or a denial of a petition
19 under paragraph (12) shall be judicially reviewable
20 in the manner specified by section 16(b)(2).

21 “(14) EXCEPTION TO REQUIREMENTS.—If the
22 Administrator finds it necessary to issue a suspen-
23 sion order under subsection (c), the Administrator
24 may waive the requirements of paragraphs (3) and
25 (4) of this subsection.”.

1 **SEC. 103. PESTICIDES IN REVIEW.**

2 If the Administrator, on or before January 1, 1993,
3 has published a document instituting a special review pro-
4 ceeding or public interim administrative review proceeding
5 with respect to a particular pesticide or active ingredient
6 thereof, the Administrator may, in lieu of proceeding
7 under section 6(b) of the Federal Insecticide, Fungicide,
8 and Rodenticide Act as amended by the Food Quality Pro-
9 tection Act of 1993, elect to continue such review proceed-
10 ing and, upon its completion, take action as warranted in
11 accordance with sections 3(c)(6), 6(b), and 6(d) as those
12 sections were in effect on the day before the date of enact-
13 ment of the Food Quality Protection Act of 1993.

14 **SEC. 104. SUSPENSION.**

15 (a) SECTION 6(c)(1).—The second sentence of sec-
16 tion 6(c)(1) (7 U.S.C. 136d(c)(1)) is revised to read: “Ex-
17 cept as provided in paragraph (3), no order of suspension
18 may be issued under this subsection unless the Adminis-
19 trator has issued, or at the same time issues, a proposed
20 rule under subsection (b).”.

21 (b) SECTION 6(c)(3).—Section 6(c)(3) (7 U.S.C.
22 136d(c)(1)) is amended by inserting after the first sen-
23 tence the following new sentence: “The Administrator may
24 issue an emergency order under this paragraph before is-
25 suing a proposed rule under subsection (b), provided that

1 the Administrator shall proceed expeditiously to issue a
2 proposed rule.”.

3 **SEC. 105. TOLERANCE REEVALUATION AS PART OF**
4 **REREGISTRATION.**

5 Section 4(g) (7 U.S.C. 136b(g)) is amended in para-
6 graph (2) by adding at the end the following:

7 “(E) As soon as the Administrator has
8 sufficient information with respect to the die-
9 tary risk of a particular active ingredient, but
10 in any event no later than the time the Admin-
11 istrator makes a determination under subpara-
12 graph (C) or (D) with respect to pesticides con-
13 taining a particular active ingredient, the Ad-
14 ministrator shall—

15 “(i) reassess each associated tolerance
16 and exemption from the requirement for a
17 tolerance issued under section 408 of the
18 Federal Food, Drug, and Cosmetic Act (21
19 U.S.C. 346a),

20 “(ii) determine whether such tolerance
21 or exemption meets the requirements of
22 that Act,

23 “(iii) determine whether additional
24 tolerances or exemptions should be issued,

“(iv) publish in the Federal Register a notice setting forth the determinations made under this subparagraph, and

“(v) commence promptly such proceedings under this Act and section 408 of the Federal Food, Drug, and Cosmetic Act as are warranted by such determinations.”.

SEC. 106. SCIENTIFIC ADVISORY PANEL.

The first sentence of section 25(d) (7 U.S.C. 136w(d)) is amended by striking out “The Administrator shall” and inserting in lieu thereof “(1) IN GENERAL.—The Administrator shall” and such section is amended by adding at the end the following:

“(2) SCIENCE REVIEW BOARD.—There is established a Science Review Board to consist of 60 scientists who shall be available to the Scientific Advisory Panel to assist in reviews conducted by the Panel. The Scientific Advisory Panel shall select the scientists from 60 nominations submitted each by the National Science Foundation and the National Institutes of Health. Members of the Board shall be compensated in the same manner as members of the Panel.”.

1 **SEC. 107. CONFORMING AMENDMENTS.**

2 (a) SECTION 3(c)(6).—Section 3(c)(6) (7 U.S.C.
3 136a(c)(6)) is amended to read as follows:

4 “(6) DENIAL OF APPLICATION FOR REGISTRA-
5 TION.—

6 “(A) Except as provided in subparagraph
7 (B), if the Administrator proposes to deny an
8 application for registration because it does not
9 satisfy the requirements of paragraph (5), the
10 Administrator shall notify the applicant of the
11 proposal and the reasons (including the factual
12 basis thereof). Unless the applicant makes the
13 necessary corrections to the application and no-
14 tifies the Administrator thereof during the 30-
15 day period beginning with the day after the
16 date the applicant receives the notice, or during
17 that time the applicant submits a request for a
18 hearing, the Administrator may issue an order
19 denying the application. If during that time the
20 Administrator does not receive such corrections
21 to the application or such a request for hearing,
22 the Administrator may issue an order denying
23 the application. Such an order shall be pub-
24 lished in the Federal Register and shall not be
25 subject to judicial review. If during that time
26 the Administrator receives a request for a hear-

ing, a hearing shall be conducted under section 6(d) of the Act. If such a hearing is held, a decision after completion of such hearing shall be final and shall be subject to judicial review under section 16(b)(1) of this Act.

“(B) The Administrator may deny an application for registration because it does not comply with the requirements of a rule issued under section 6(b) of this Act. The Administrator shall notify the applicant of such denial. Such notice shall explain why the application does not comply with such requirements and shall state that the applicant may petition to amend or revoke such rule under section 6(b)(12) of this Act.”.

(b) SECTION 3(c)(8).—Section 3(c)(8) (7 U.S.C. 136a(c)(8)) is repealed.

(c) SECTION 3(d).—Section 3(d) (7 U.S.C. 136a(dd)) is amended—

(1) in paragraph (1)(A), by striking out “on the initial classification and registered pesticides” and inserting in lieu thereof “under section 6(b) of this Act. Registered pesticides”; and

(2) in paragraph (2), by striking out all that follows “on the environment,” and inserting in lieu

1 thereof “the Administrator may initiate a proceeding
2 under section 6(b) of the Act.”.

3 (d) SECTION 4(e).—Section 4(e)(3)(B)(iii)(III) (7
4 U.S.C. 136b(e)(3)(B)(iii)(III)) is amended—

5 (1) by striking out “section 6(d), except that
6 the” and inserting in lieu thereof “section 6(d).
7 The”; and

8 (2) by inserting after “guidelines.” the follow-
9 ing: “If a hearing is held, a decision after completion
10 of such hearing shall be final.”;

11 (e) SECTION 6(c).—Section 6(c) (7 U.S.C. 136d(c))
12 is amended in paragraph (4) by striking out “section 16”
13 and inserting in lieu thereof “section 16(b)(1)”.

14 (f) SECTION 6(d).—Section 6(d) (7 U.S.C. 136d(d))
15 is amended—

16 (1) by revising the first sentence to read as fol-
17 lows: “If a hearing is requested pursuant to section
18 3(e)(2)(B)(iv), 3(e)(6), 4(e)(3)(B)(iii)(III), 6(c)(2),
19 or 6(e)(2), such hearing shall be held for the pur-
20 pose of receiving evidence relevant and material to
21 the issues raised by the request for hearing.”; and

22 (2) by striking all that follows the eighth sen-
23 tence and inserting the following: “A hearing under
24 this subsection shall be held in accordance with the
25 provisions of sections 554, 556, and 557 of title 5,

1 United States Code. As soon as practicable after the
2 completion of the hearing, the Administration shall
3 issue a final order setting forth the Administrator's
4 decision. Such order and decision shall be based only
5 on substantial evidence of record of such hearing,
6 shall set forth detailed findings of fact upon which
7 the order is based, and shall be subject to judicial
8 review under section 16(b)(1).".

9 (g) SECTION 16(a).—Section 16(a) (7 U.S.C.
10 136n(a)) is amended by inserting "or a proceeding under
11 section 6(b)" after "a hearing".

12 (h) SECTION 16(b).—Section 16(b) (17 U.S.C.
13 136n(b)) is amended—

14 (1) by striking out "(b) REVIEW BY COURT OF
15 APPEALS.—In the case of" and inserting in lieu
16 thereof the following:

17 "(b) REVIEW BY COURT OF APPEALS.—

18 "(1) REVIEW OF CERTAIN ORDERS.—In the
19 case of";

20 (2) by striking "under this section" in the sixth
21 sentence of paragraph (1) (as so designated) and in-
22 serting "under this paragraph"; and

23 (3) by adding at the end the following new
24 paragraph:

1 “(2) REVIEW OF CERTAIN RULES.—In the case
2 of actual controversy as to the validity of any rule
3 issued by the Administrator under section 6(b)(9),
4 any decision by the Administrator under section
5 6(b)(4) or 6(b)(9) not to issue a proposed rule or to
6 withdraw a proposed rule, or any denial of a petition
7 to revoke or amend a final rule under section
8 6(b)(12), any person who will be adversely affected
9 by such rule or decision and who has filed comments
10 in the proceeding leading to the rule or decision may
11 obtain judicial review by filing a petition in the United
12 States court of appeals for the circuit wherein
13 such person resides or has a place of business, with-
14 in 60 days after the entry of such order. A copy of
15 the petition shall be forthwith transmitted to the Ad-
16 ministrator or any officer designated by the Admin-
17 istrator for that purpose, and thereupon the Admin-
18 istrator shall file in court the record of the proceed-
19 ings on which the Administrator based such rule or
20 decision, as provided in section 2112 of title 28,
21 United States Code. Upon the filing of such petition
22 the court shall have exclusive jurisdiction to affirm
23 or set aside such rule or decision in whole or in part.
24 The standard review shall be that set forth in sec-
25 tion 706 of title 5, United States Code. The judg-

1 ment of the court under this paragraph shall be
2 final, subject to review by the Supreme Court upon
3 certiorari or certification as provided in section 1254
4 of title 28 of the United States Code. The com-
5 mencement of proceedings under this section shall
6 not, unless specifically ordered by the court to the
7 contrary, operate as a stay of an order.”.

8 (i) SECTION 25(a).—Section 25(a) (7 U.S.C.
9 136w(a)) is amended by adding a new paragraph (5) at
10 the end, to read as follows:

11 “(5) EXCEPTION.—The requirements of this
12 subsection shall not apply to any rule or rulemaking
13 proceeding under section 6(b).”.

14 (j) SECTION 25(d).—Section 25(d) (7 U.S.C.
15 136w(d)) is amended—

16 (1) in the first sentence by striking out “in no-
17 tices of intent issued under subsection 6(b) and”;
18 and

19 (2) in the second sentence by striking out “no-
20 tices of intent and” and by striking out “section
21 6(b) or”.

22 (k) SECTION 25(e).—Section 25(e) (7 U.S.C.
23 136w(e)) is amended by striking out the period at the end
24 of the second sentence and substituting “, except for any
25 action that may be taken under section 6(b).”.

1 **TITLE II—DATA COLLECTION**

2 **SEC. 201. COLLECTION OF PESTICIDE USE INFORMATION.**

3 The Secretary of Agriculture shall collect data of
4 Statewide or regional significance on the use of pesticides
5 to control pests and diseases of major crops and crops of
6 dietary significance, including fruits and vegetables. Such
7 data shall be collected by surveys of farmers or from other
8 sources offering statistically reliable data. The Secretary
9 shall, as appropriate, coordinate with the Administrator
10 of the Environmental Protection Agency in the design of
11 such surveys and make available to the Administrator the
12 aggregate results of such surveys to assist the Adminis-
13 trator in developing exposure calculations and benefits de-
14 terminations with respect to pesticide regulatory decisions.

15 **SEC. 202. INTEGRATED PEST MANAGEMENT.**

16 Section 28(c) of the Federal Insecticide, Fungicide,
17 and Rodenticide Act (7 U.S.C. 136w-3(c)) is amended—

18 (1) by designating the text of such section as
19 paragraph (1) with the margin indented one em, and

20 (2) by adding at the end the following:

21 “(2) The Administrator and the Secretary of Agri-
22 culture shall research, develop, and disseminate integrated
23 pest management techniques and other pest control meth-
24 ods that enable producers to reduce or eliminate applica-
25 tions of pesticides which pose a greater than negligible die-

1 tary risk to humans, with a special focus on crops critical
2 to a balanced, healthy diet and which are considered as
3 minor crops in terms of acreage produced.”.

4 **TITLE III—AMENDMENTS TO THE FED-**
5 **ERAL FOOD, DRUG, AND COSMETIC**
6 **ACT**

7 **SEC. 301. REFERENCE.**

8 Whenever in this title an amendment is expressed in
9 terms of an amendment to a section or other provision,
10 or refers to a section or other provision, the reference shall
11 be considered to be made to a section or other provision
12 of the Federal Food, Drug, and Cosmetic Act.

13 **SEC. 302. DEFINITIONS.**

14 (a) Section 201(q) (21 U.S.C. 321(q)) is amended to
15 read as follows:

16 “(q)(1) The term ‘pesticide chemical’ means—

17 “(A) any substance that is a pesticide within
18 the meaning of the Federal Insecticide, Fungicide,
19 and Rodenticide Act, or

20 “(B) any active or inert ingredient of a pes-
21 ticide within the meaning of the Federal Insecticide,
22 Fungicide, and Rodenticide Act.

23 “(2) The term ‘pesticide chemical residue’ means a
24 residue in or on raw agricultural commodity or processed
25 food of—

1 “(A) a pesticide chemical, or

2 “(B) any other added substance that is present
3 in the commodity or food primarily as a result of the
4 metabolism or other degradation of a pesticide
5 chemical.

6 “(3) Notwithstanding paragraphs (1) and (2), the
7 Administrator may by regulation except a substance from
8 the definition of ‘pesticide chemical’ or ‘pesticide chemical
9 residue’ if—

10 “(A) its occurrence as a residue on a raw agri-
11 cultural commodity or processed food is attributable
12 primarily to natural causes or to human activities
13 not involving the use of any substances for a pes-
14 ticial purpose in the production, storage, process-
15 ing, or transportation of any raw agricultural com-
16 modity or processed food, and

17 “(B) the Administrator, after consultation with
18 the Secretary, determines that the substance more
19 appropriately should be regulated under one or more
20 provisions of this Act other than sections
21 402(a)(2)(B) and 408.”.

22 (b) Paragraphs (1) and (2) of section 201(s) (21
23 U.S.C. 321(s)) are amended to read as follows:

24 “(1) a pesticide chemical residue in or on a raw
25 agricultural commodity or processed food; or

1 “(2) a pesticide chemical; or”.

2 (c) Section 201 (21 U.S.C. 321) is amended by add-
3 ing at the end the following:

4 “(bb) The term ‘processed food’ means any food
5 other than a raw agricultural commodity and includes any
6 raw agricultural commodity that has been subject to proc-
7 essing, such as canning, cooking, freezing, dehydration, or
8 milling.

9 “(cc) The term ‘Administrator’ means the Adminis-
10 trator of the United States Environmental Protection
11 Agency.”.

12 **SEC. 303. PROHIBITED ACTS.**

13 Section 301(j) (21 U.S.C. 331(j)) is amended—

14 (1) by striking the period at the end; and

15 (2) by adding at the end “, or the violation of
16 section 408(g)(2) or any regulation issued under
17 that section.”.

18 **SEC. 304. ADULTERATED FOOD.**

19 Section 402(a)(2) (21 U.S.C. 342(a)(2)) is amended
20 to read as follows:

21 “(2)(A) if it bears or contains any added poi-
22 sonous or added deleterious substance (other than a
23 substance that is a pesticide chemical residue in or
24 on a raw agricultural commodity or processed food,
25 a food additive, a color additive, or a new animal

1 drug) that is unsafe within the meaning of section
2 406;

3 “(B) if it bears or contains a pesticide chemical
4 residue that is unsafe within the meaning of section
5 408(a); or

6 “(C) if it is or if it bears or contains—

7 “(i) any food additive that is unsafe within
8 the meaning of section 409, or

9 “(ii) a new animal drug (or conversion
10 product thereof) that is unsafe within the
11 meaning of section 512; or”.

12 **SEC. 305. TOLERANCES AND EXEMPTIONS FOR PESTICIDE**
13 **CHEMICAL RESIDUES.**

14 Section 408 (21 U.S.C. 346a) is amended to read as
15 follows:

16 **“TOLERANCES AND EXEMPTIONS FOR PESTICIDE**
17 **CHEMICAL RESIDUES**

18 **“SEC. 408. (a) REQUIREMENT FOR TOLERANCE OR**
19 **EXEMPTION.—**

20 **“(1) GENERAL RULE.—**For the purposes of this
21 section, the term ‘food,’ when used as a noun with-
22 out modification, shall mean a raw agricultural com-
23 modity or processed food. Except as provided in
24 paragraph (2) or (3), any pesticide chemical residue
25 in or on a food shall be deemed unsafe for the pur-
26 pose of section 402(a)(2)(B) unless—

1 “(A) a tolerance for such pesticide chemi-
2 cal residue in or on such food is in effect under
3 this section and the concentration of the residue
4 is within the limits of the tolerance, or

5 “(B) an exemption from the requirement
6 of a tolerance is in effect under this section for
7 the pesticide chemical residue.

8 “(2) PROCESSED FOOD.—Notwithstanding
9 paragraph (1)—

10 “(A) if a tolerance is in effect under this
11 section for a pesticide chemical residue in or on
12 a raw agricultural commodity, a pesticide chem-
13 ical residue that is present in or on a processed
14 food because the food is made from that raw
15 agricultural commodity shall not be considered
16 unsafe within the meaning of section
17 402(a)(2)(B) despite the lack of a tolerance for
18 the pesticide chemical residue in or on the proc-
19 essed food if the concentration of the pesticide
20 chemical residue in the processed food when
21 ready for consumption or use is not greater
22 than the tolerance prescribed for the pesticide
23 chemical residue in the raw agricultural com-
24 modity.

1 “(B) If an exemption from the requirement
2 for a tolerance is in effect under this section for
3 a pesticide chemical residue in or on a raw agri-
4 cultural commodity, a pesticide chemical residue
5 that is present in or on a processed food be-
6 cause the food is made from that raw agricul-
7 tural commodity shall not be considered unsafe
8 within the meaning of section 402(a)(2)(B).

9 “(3) RESIDUES OF DEGRADATION PRODUCTS.—

10 If a pesticide chemical residue is present in or on a
11 food because it is a metabolite or other degradation
12 product of a precursor substance that itself is a pes-
13 ticide chemical or pesticide chemical residue, such a
14 residue shall not be considered to be unsafe within
15 the meaning of section 402(a)(2)(B) despite the lack
16 of a tolerance or exemption from the need for a tol-
17 erance for such residue in or on such food if—

18 “(A) the Administrator has not determined
19 that the degradation product is likely to pose
20 any potential health risk from dietary exposure
21 that is of a different type than, or of a greater
22 significance than, any risk posed by dietary ex-
23 posure to the precursor substance, and

24 “(B) either—

1 “(i) a tolerance is in effect under this
2 section for residues of the precursor sub-
3 stance in or on the food, and the combined
4 level of residues of the degradation product
5 and the precursor substance in or on the
6 food is at or below the stoichiometrically
7 equivalent level that would be permitted by
8 the tolerance if the residue consisted only
9 of the precursor substance rather than the
10 degradation product, or

11 “(ii) an exemption from the need for
12 a tolerance is in effect under this section
13 for residues of the precursor substance in
14 or on the food, and

15 “(C) the tolerance or exemption for resi-
16 dues of the precursor substance does not state
17 that it applies only to particular named sub-
18 stances or states that it does not apply to resi-
19 dues of the degradation product.

20 “(4) EFFECT OF TOLERANCE OR EXEMP-
21 TION.—While a tolerance or exemption from the re-
22 quirement for a tolerance is in effect under this sec-
23 tion for a pesticide chemical residue with respect to
24 any food, the food shall not by reason of bearing or
25 containing any amount of such a residue be consid-

1 ered to be adulterated within the meaning of section
2 402(a)(1).

3 “(b) AUTHORITY AND STANDARD FOR TOLER-
4 ANCES.—

5 “(1) AUTHORITY.—The Administrator may
6 issue regulations establishing, modifying, or revoking
7 a tolerance for a pesticide chemical residue in or on
8 a food—

9 “(A) in response to a petition filed under
10 subsection (d), or

11 “(B) on the Administrator’s initiative
12 under subsection (e).

13 “(2) STANDARD.—(A) A tolerance may not be
14 established for a pesticide chemical residue in or on
15 a food at a level that is higher than a level that the
16 Administrator determines is adequate to protect the
17 public health.

18 “(B) The Administrator shall modify or revoke
19 a tolerance if it is at a level higher than the level
20 that the Administrator determines is adequate to
21 protect the public health.

22 “(C) In making a determination under this
23 paragraph the Administrator shall take into account,
24 among other relevant factors, the validity, complete-
25 ness, and reliability of the available data from stud-

ies of the pesticide chemical residue, the nature of any toxic effects shown to be caused by the pesticide chemical in such studies, available information and reasonable assumptions concerning the relationship of the results of such studies to human risk, available information and reasonable assumptions concerning the dietary exposure levels of food consumers (and major identifiable subgroups of food consumers) to the pesticide chemical residue, and available information and reasonable assumptions concerning the variability of the sensitivities of major identifiable groups and shall consider other factors to the extent required by subparagraph (F).

“(D) For purposes of subparagraph (A), a tolerance level for a pesticide chemical residue in or on a food shall be deemed to be adequate to protect the public health if the dietary risk posed to food consumers by such level of the pesticide chemical residue is negligible. The Administrator shall by regulation set forth the factors and methods for determining whether such a risk is negligible.

“(E) Where reliable data are available, the Administrator shall calculate the dietary risk posed to food consumers by a pesticide chemical on the basis of the percent of food actually treated with the pes-

1 pesticide chemical and the actual residue levels of the
2 pesticide chemical that occur in food. In particular,
3 the Administrator shall take into account aggregate
4 pesticide use and residue data collected by the De-
5 partment of Agriculture.

6 “(F) For purposes of subparagraph (A), a level
7 of a pesticide chemical residue in or on a food that
8 poses a greater than negligible dietary risk to con-
9 sumers of the food shall be deemed to be adequate
10 to protect the public health if the Administrator de-
11 termines that such risk is not unreasonable
12 because—

13 “(i) use of the pesticide that produces the
14 residue protects humans or the environment
15 from adverse effects on public health or welfare
16 that would, directly or indirectly, result in
17 greater risk to the public or the environment
18 than the dietary risk from the pesticide chemi-
19 cal residue; or

20 “(ii) use of the pesticide avoids risks to
21 workers, the public, or the environment that
22 would be expected to result from the use of an-
23 other pesticide or pest control method on the
24 same food and that are greater than the risks

1 that result from dietary exposure to the pes-
2 ticide chemical residue; or

3 “(iii) the unavailability of the pesticide
4 would limit the availability to consumers of an
5 adequate, wholesome, and economical food sup-
6 ply, taking into account regional and domestic
7 effects, and such adverse effects are likely to
8 outweigh the risk posed by the pesticide resi-
9 due.

10 In making the determination under this subpara-
11 graph, the Administrator shall not consider the ef-
12 fects on any pesticide registrant, manufacturer, or
13 marketer of a pesticide.

14 “(3) LIMITATIONS.—(A) A tolerance may be is-
15 sued under the authority of paragraph (2)(E) only
16 if the Administrator has assessed the extent to
17 which efforts are being made to develop either an al-
18 ternative method of pest control or an alternative
19 pesticide chemical for use on such commodity or
20 food that would meet the requirements of paragraph
21 (2)(D).

22 “(B) A tolerance for a pesticide chemical resi-
23 due in or on a food shall not be established by the
24 Administrator unless the Administrator determines,
25 after consultation with the Secretary, that there is

1 a practical method for detecting and measuring the
2 levels of the pesticide chemical residue in or on the
3 food.

4 “(C) A tolerance for a pesticide chemical resi-
5 due in or on a food shall not be established at a level
6 lower than the limit of detection of the method for
7 detecting and measuring the pesticide chemical resi-
8 due specified by the Administrator under subpara-
9 graph (B).

10 “(4) INTERNATIONAL STANDARDS.—In estab-
11 lishing a tolerance for a pesticide chemical residue in
12 or on a food, the Administrator shall take into ac-
13 count any maximum residue level for the chemical in
14 or on the food that has been established by the
15 Codex Alimentarius Commission. The Administrator
16 shall determine whether the Codex maximum residue
17 level is adequate to protect the health of United
18 States’ consumers and whether the data supporting
19 the maximum residue level are valid, complete, and
20 reliable. If the Administrator determines not to
21 adopt a Codex maximum residue level, the Adminis-
22 trator shall publish a notice in the Federal Register
23 setting forth the reasons.

24 “(c) AUTHORITY AND STANDARD FOR EXEMP-
25 TIONS.—

1 “(1) AUTHORITY.—The Administrator may
2 issue a regulation establishing, modifying, or revok-
3 ing an exemption from the requirement for a toler-
4 ance for a pesticide chemical residue in or on a
5 food—

6 “(A) in response to a petition filed under
7 subsection (d), or

8 “(B) on the Administrator’s initiative
9 under subsection (e).

10 “(2) STANDARD.—(A) An exemption from the
11 requirement for a tolerance for a pesticide chemical
12 residue in or on a food may be established only if
13 the Administrator determines that a tolerance is not
14 needed to protect the public health, in view of the
15 levels of dietary exposure to the pesticide chemical
16 residue that could reasonably be expected to occur.

17 “(B) An exemption from the requirement for a
18 tolerance for a pesticide chemical residue in or on a
19 food shall be revoked if the Administrator, in re-
20 sponse to a petition for the revocation of the exemp-
21 tion or at the Administrator’s own initiative deter-
22 mines that the exemption does not satisfy the cri-
23 terion of subparagraph (A).

24 “(C) In making a determination under this sub-
25 paragraph, the Administrator shall take into ac-

1 count, among other relevant factors, the factors set
2 forth in subsection (b)(2)(C).

3 “(3) LIMITATION.—An exemption from the re-
4 quirement for a tolerance for a pesticide chemical
5 residue in or on a food shall not be established by
6 the Administrator unless the Administrator deter-
7 mines, after consultation with the Secretary—

8 “(A) that there is a practical method for
9 detecting and measuring the levels of such pes-
10 ticide chemical residue in or on such food; or

11 “(B) that there is no need for such a
12 method, and states the reasons for such deter-
13 mination in the order issuing the regulation es-
14 tablishing or modifying the regulation.

15 “(d) PETITION FOR TOLERANCE OR EXEMPTION.—

16 “(1) PETITIONS AND PETITIONERS.—Any per-
17 son may file with the Administrator a petition pro-
18 posing the issuance of a regulation—

19 “(A) establishing, modifying, or revoking a
20 tolerance for a pesticide chemical residue in or
21 on a food, or

22 “(B) establishing or revoking an exemption
23 from the requirement of a tolerance for such a
24 residue.

25 “(2) PETITION CONTENTS.—

41

1 “(A) ESTABLISHMENT.—A petition under
2 paragraph (1) to establish a tolerance or ex-
3 emption for a pesticide chemical residue shall
4 be supported by such data and information as
5 are specified in regulations issued by the Ad-
6 ministrator, including—

7 “(i)(I) an informative summary of the
8 petition and of the data, information, and
9 arguments submitted or cited in support of
10 the petition,

11 “(II) a statement that the petitioner
12 agrees that such summary or any informa-
13 tion it contains may be published as a part
14 of the notice of filing of the petition to be
15 published under this subsection and as
16 part of a proposed or final regulation is-
17 sued under this section,

18 “(ii) the name, chemical identity, and
19 composition of the pesticide chemical resi-
20 due and of the pesticide chemical that pro-
21 duces the residue,

22 “(iii) data showing the recommended
23 amount, frequency, method, and time of
24 application of that pesticide chemical,

1 “(iv) full reports of tests and inves-
2 tigations made with respect to the safety of
3 the pesticide chemical, including full infor-
4 mation as to the methods and controls
5 used in conducting those tests and inves-
6 tigations,

7 “(v) full reports of tests and inves-
8 tigations made with respect to the nature
9 and amount of the pesticide chemical resi-
10 due that is likely to remain in or on the
11 food, including a description of the analyt-
12 ical methods used,

13 “(vi) a practical method for detecting
14 and measuring the levels of the pesticide
15 chemical residue in or on the food, or a
16 statement why such a method is not need-
17 ed,

18 “(vii) practical methods for removing
19 any amount of the residue that would ex-
20 ceed any proposed tolerance,

21 “(viii) a proposed tolerance for the
22 pesticide chemical residue, if a tolerance is
23 proposed,

24 “(ix) all relevant data bearing on the
25 physical or other technical effect that the

1 pesticide chemical is intended to have and
2 the quantity of the pesticide chemical that
3 is required to produce the effect,

4 “(x) if the petition relates to a toler-
5 ance for a processed food, reports of inves-
6 tigations conducted using the processing
7 method(s) used to produce that food,

8 “(xi) such information as the Admin-
9 istrator may require to make the deter-
10 mination under subsection (b)(2)(E), and

11 “(xii) such other data and information
12 as the Administrator requires by regulation
13 to support the petition.

14 If information or data required by this subpara-
15 graph is available to the Administrator, the per-
16 son submitting the petition may cite the avail-
17 ability of the information or data in lieu of sub-
18 mitting it. The Administrator may require a pe-
19 tition to be accompanied by samples of the pes-
20 ticide chemical with respect to which the peti-
21 tion is filed.

22 “(B) MODIFICATION OR REVOCATION.—

23 The Administrator may by regulation establish
24 the requirements for information and data to
25 support a petition to modify or revoke a toler-

1 ance or to revoke an exemption from the re-
2 quirement for a tolerance.

3 “(3) NOTICE.—A notice of the filing of a peti-
4 tion that the Administrator determines has met the
5 requirements of paragraph (2) shall be published by
6 the Administrator within 30 days after such deter-
7 mination. The notice shall announce the availability
8 of a description of the analytical methods available
9 to the Administrator for the detection and measure-
10 ment of the pesticide chemical residue with respect
11 to which the petition is filed or shall set forth the
12 petitioner’s statement of why such a method is not
13 needed. The notice shall include the summary re-
14 quired by paragraph (2)(A)(i).

15 “(4) ACTIONS BY THE ADMINISTRATOR.—The
16 Administrator shall, after giving due consideration
17 to a petition filed under paragraph (1) and any
18 other information available to the Administrator—

19 “(A) issue a final regulation (which may
20 vary from that sought by the petition) estab-
21 lishing, modifying, or revoking a tolerance for
22 the pesticide chemical residue or an exemption
23 of the pesticide chemical residue from the re-
24 quirement of a tolerance;

1 “(B) issue a proposed regulation under
2 subsection (e), and thereafter either issue a
3 final regulation under subsection (e) or an
4 order denying the petition; or

5 “(C) issue an order denying the petition.

6 “(5) EFFECTIVE DATE.—A regulation issued
7 under paragraph (4) shall take effect upon publica-
8 tion.

9 “(6) FURTHER PROCEEDINGS.—

10 “(A) Within 60 days after a regulation or
11 order is issued under paragraph (4), subsection
12 (e)(1), or subsection (f)(1), any person may file
13 objections thereto with the Administrator, speci-
14 fying with particularity the provisions of the
15 regulation or order deemed objectionable and
16 stating reasonable grounds therefor. If the reg-
17 ulation or order was issued in response to a pe-
18 tition under paragraph (d)(1), a copy of each
19 objection filed by a person other than the peti-
20 tioner shall be served by the Administrator on
21 the petitioner.

22 “(B) An objection may include a request
23 for a public evidentiary hearing upon the objec-
24 tion. The Administrator shall, upon the initia-
25 tive of the Administrator or upon the request of

1 an interested person and after due notice, hold
2 a public evidentiary hearing if and to the extent
3 the Administrator determines that such a public
4 hearing is necessary to receive factual evidence
5 relevant to material issues of fact raised by the
6 objections. The presiding officer in such a hear-
7 ing may authorize a party to obtain discovery
8 from other persons and may upon a showing of
9 good cause made by a party issue a subpoena
10 to compel testimony or production of documents
11 from any person. The presiding officer shall be
12 governed by the Federal Rules of Civil Proce-
13 dure in making any order for the protection of
14 the witness or the content of documents pro-
15 duced and shall order the payment of reason-
16 able fees and expenses as a condition to requir-
17 ing testimony of the witness. On contest, such
18 a subpoena may be enforced by a Federal dis-
19 trict court.

20 “(C) As soon as practicable after receiving
21 the arguments of the parties, the Administrator
22 shall issue an order stating the action taken
23 upon each such objection and setting forth any
24 revision to the regulation or prior order that the
25 Administrator has found to be warranted. If a

1 hearing was held under subparagraph (B), such
2 order and any revision to the regulation or prior
3 order shall, with respect to questions of fact at
4 issue in the hearing, be based only on substan-
5 tial evidence of record at such hearing, and
6 shall set forth in detail the findings of facts and
7 the conclusions of law or policy upon which the
8 order or regulation is based.

9 “(D) An order issued under this paragraph
10 ruling on an objection shall not take effect be-
11 fore the 90th day after its publication unless
12 the Administrator finds that emergency condi-
13 tions exist necessitating an earlier effective
14 date, in which event the Administrator shall
15 specify in the order the Administrator’s find-
16 ings as to such conditions.

17 “(7) JUDICIAL REVIEW.—(A) In a case of ac-
18 tual controversy as to the validity of any order is-
19 sued under paragraph (6) or any regulation that is
20 the subject of such an order, any person who will be
21 adversely affected by such order or regulation may
22 obtain judicial review by filing in the United States
23 Court of Appeals for the circuit wherein that person
24 resides or has its principal place of business, or in
25 the United States Court of Appeals for the District

1 of Columbia Circuit, within 60 days after publication
2 of such order, a petition praying that the order or
3 regulation be set aside in whole or in part.

4 “(B) A copy of the petition shall be forthwith
5 transmitted by the clerk of the court to the Adminis-
6 trator, or any officer designated by the Adminis-
7 trator for that purpose, and thereupon the Adminis-
8 trator shall file in the court the record of the pro-
9 ceedings on which the Administrator based the order
10 or regulation, as provided in section 2112 of title 28,
11 United States Code. Upon the filing of such a peti-
12 tion, the court shall have exclusive jurisdiction to af-
13 firm or set aside the order or regulation complained
14 of in whole or in part. The findings of the Adminis-
15 trator with respect to questions of fact shall be sus-
16 tained only if supported by substantial evidence
17 when considered on the record as a whole.

18 “(C) If a party applies to the court for leave to
19 adduce additional evidence, and shows to the satis-
20 faction of the court that the additional evidence is
21 material and that there were reasonable grounds for
22 the failure to adduce the evidence in the proceeding
23 before the Administrator, the court may order that
24 the additional evidence (and evidence in rebuttal
25 thereof) shall be taken before the Administrator in

1 the manner and upon the terms and conditions the
2 court deems proper. The Administrator may modify
3 prior findings as to the facts by reason of the addi-
4 tional evidence so taken and may modify the order
5 or regulation accordingly. The Administrator shall
6 file with the court any such modified finding, order,
7 or regulation.

8 “(D) The judgment of the court affirming or
9 setting aside, in whole or in part, any order under
10 paragraph (6) and any regulation which is the sub-
11 ject of such an order shall be final, subject to review
12 by the Supreme Court of the United States as pro-
13 vided in section 1254 of title 28 of the United States
14 Code. The commencement of proceedings under this
15 paragraph shall not, unless specifically ordered by
16 the court to the contrary, operate as a stay of a reg-
17 ulation or order.

18 “(E) Any issue as to which review is or was ob-
19 tainable under paragraph (6) and this paragraph
20 shall not be the subject of judicial review under any
21 other provision of law.

22 “(e) ACTION ON ADMINISTRATOR’S OWN INITIA-
23 TIVE.—

24 “(1) GENERAL RULE.—The Administrator may
25 issue a regulation—

1 “(A) establishing, modifying, or revoking a
2 tolerance for a pesticide chemical or a pesticide
3 chemical residue,

4 “(B) establishing or revoking an exemption
5 of a pesticide chemical residue from the require-
6 ment of a tolerance, or

7 “(C) establishing general procedures and
8 requirements to implement this section.

9 A regulation issued under this paragraph shall be-
10 come effective upon its publication.

11 “(2) NOTICE.—Before issuing a final regulation
12 under paragraph (1), the Administrator shall issue
13 a notice of proposed rulemaking and provide a pe-
14 riod of not less than 60 days for public comment on
15 the proposed regulation, except that a shorter period
16 for comment may be provided if the Administrator
17 for good cause finds that it would be contrary to the
18 public interest to do so and states the reasons for
19 the finding in the notice of proposed rulemaking.
20 The Administrator shall provide an opportunity for
21 a public hearing during the rulemaking under proce-
22 dures provided in subsection (d)(6)(B).

23 “(f) SPECIAL DATA REQUIREMENTS.—

24 “(1) REQUIRING SUBMISSION OF ADDITIONAL
25 DATA.—If the Administrator determines that addi-

1 tional data or information are reasonably required to
2 support the continuation of a tolerance or exemption
3 that is in effect under this section for a pesticide
4 chemical residue on a food, the Administrator
5 shall—

6 “(A) issue a notice requiring the persons
7 holding the pesticide registrations associated
8 with such tolerance or exemption to submit the
9 data or information under section 3(c)(2)(B) of
10 the Federal Insecticide, Fungicide, and
11 Rodenticide Act,

12 “(B) issue a rule requiring that testing be
13 conducted on a substance or mixture under sec-
14 tion 4 of the Toxic Substances Control Act, or

15 “(C) publish in the Federal Register, after
16 first providing notice and an opportunity for
17 comment of not less than 90 days’ duration, an
18 order—

19 “(i) requiring the submission to the
20 Administrator by one or more interested
21 persons of a notice identifying the person
22 or persons who will submit the required
23 data and information,

24 “(ii) describing the type of data and
25 information required to be submitted to

1 the Administrator and stating why the
2 data and information could not be obtained
3 under the authority of section 3(c)(2)(B)
4 of the Federal Insecticide, Fungicide, and
5 Rodenticide Act or section 4 of the Toxic
6 Substances Control Act,

7 “(iii) describing the reports to the Ad-
8 ministrator required to be prepared during
9 and after the collection of the data and in-
10 formation,

11 “(iv) requiring the submission to the
12 Administrator of the data, information,
13 and reports referred to in clauses (ii) and
14 (iii), and

15 “(v) establishing dates by which the
16 submissions described in clauses (i) and
17 (iv) must be made.

18 The Administrator may revise any such order to cor-
19 rect an error.

20 “(2) NONCOMPLIANCE.—If a submission re-
21 quired by a notice issued in accordance with para-
22 graph (1)(A) or an order issued under paragraph
23 (1)(B) is not made by the time specified in such no-
24 tice or order, the Administrator may by order pub-

1 lished in the Federal Register modify or revoke the
2 tolerance or exemption in question.

3 “(3) REVIEW.—An order issued under this sub-
4 section shall be effective upon publication and shall
5 be subject to review in accordance with paragraphs
6 (6) and (7) of subsection (d).

7 “(g) CONFIDENTIALITY AND USE OF DATA.—

8 “(1) GENERAL RULE.—Data and information
9 that are submitted to the Administrator under this
10 section in support of a tolerance shall be entitled to
11 confidential treatment for reasons of business con-
12 fidentiality and to exclusive use and data compensa-
13 tion, to the same extent provided by sections 3 and
14 10 of the Federal Insecticide, Fungicide and
15 Rodenticide Act.

16 “(2) EXCEPTIONS.—Data that are entitled to
17 confidential treatment under paragraph (1) may
18 nonetheless be disclosed to the Congress of the Unit-
19 ed States, and may be disclosed, under such security
20 requirements as the Administrator may provide by
21 regulation, to—

22 “(A) employees of the United States au-
23 thorized by the Administrator to examine such
24 data in the carrying out of their official duties

1 under this Act or other Federal statutes in-
2 tended to protect the public health, or

3 “(B) contractors with the United States
4 authorized by the Administrator to examine
5 such data in the carrying out of contracts under
6 such statutes.

7 “(3) SUMMARIES.—Notwithstanding any provi-
8 sion of this subsection or other law, the Adminis-
9 trator may publish the informative summary re-
10 quired by subsection (d)(2)(A)(i) and may, in issu-
11 ing a proposed or final regulation or order under
12 this section, publish an informative summary of the
13 data relating to the regulation or order.

14 “(h) STATUS OF PREVIOUSLY ISSUED REGULA-
15 TIONS.—

16 “(1) REGULATIONS UNDER SECTION 406.—Reg-
17 ulations affecting pesticide chemical residues in or
18 on raw agricultural commodities promulgated, in ac-
19 cordance with section 701(e), under the authority of
20 section 406(a) upon the basis of public hearings in-
21 stituted before January 1, 1953, shall be deemed to
22 be regulations issued under this section and shall be
23 subject to modification or revocation under sub-
24 sections (d) and (e).

1 “(2) REGULATIONS UNDER SECTION 409.—Reg-
2 ulations that established tolerances for substances
3 that are pesticide chemical residues on or in proc-
4 essed food, or that otherwise stated the conditions
5 under which such pesticide chemicals could be safely
6 used, and that were issued under section 409 on or
7 before the date of the enactment of this paragraph,
8 shall be deemed to be regulations issued under this
9 section and shall be subject to modification or rev-
10 ocation under subsection (d) or (e).

11 “(3) REGULATIONS UNDER SECTION 408.—Reg-
12 ulations that established tolerances or exemptions
13 under this section that were issued on or before the
14 date of the enactment of this paragraph shall remain
15 in effect unless modified or revoked under subsection
16 (d) or (e).

17 “(i) TRANSITIONAL PROVISION.—If, on the day be-
18 fore the date of the enactment of this subsection, a sub-
19 stance that is a pesticide chemical was, with respect to
20 a particular pesticidal use of the substance and any result-
21 ing pesticide chemical residue in or on a particular food—

22 “(1) regarded by the Administrator or the Sec-
23 retary as generally recognized as safe for use within
24 the meaning of the provisions of section 408(a) or
25 201(s) as then in effect, or

1 “(2) regarded by the Secretary as a substance
2 described by section 201(s)(4),
3 such a pesticide chemical residue shall be regarded as ex-
4 empt from the requirement for a tolerance, as of the date
5 of enactment of this subsection. The Administrator shall
6 by regulation indicate which substances are described by
7 this subsection. An exemption under this subsection may
8 be revoked or modified as if it had been issued under sub-
9 section (c).

10 “(j) HARMONIZATION WITH ACTION UNDER OTHER
11 LAWS.—

12 “(1) LIMITATION.—Notwithstanding any other
13 provision of this Act, a final rule under this section
14 that revokes, modifies, or suspends a tolerance or
15 exemption for a pesticide chemical residue in or on
16 a food may be issued only if the Administrator has
17 first taken any necessary action under the Federal
18 Insecticide, Fungicide, and Rodenticide Act with re-
19 spect to the registration of the pesticide(s) whose
20 use results in such residue to ensure that any au-
21 thorized use of the pesticide in producing, storing,
22 processing, or transporting food that occurs after
23 the issuance of such final rule under this section will
24 not result in pesticide chemical residues on such

1 food that are unsafe within the meaning of sub-
2 section (a).

3 “(2) REVOCATION OF TOLERANCE OR EXEMP-
4 TION FOLLOWING CANCELLATION OF ASSOCIATED
5 REGISTRATIONS.—If the Administrator, acting under
6 the Federal Insecticide, Fungicide, and Rodenticide
7 Act, cancels the registration of each pesticide that
8 contains a particular pesticide chemical and that is
9 labeled for use on a particular food, or requires that
10 the registration of each such pesticide be modified to
11 prohibit its use in connection with the production,
12 storage, or transportation of such food, due in whole
13 or in part to dietary risks to humans posed by resi-
14 dues of that pesticide chemical on that food, the Ad-
15 ministrator shall revoke any tolerance or exemption
16 that allows the presence of the pesticide chemical, or
17 any pesticide chemical residue that results from its
18 use, in or on that food. The Administrator shall use
19 the procedures set forth in subsection (e) in taking
20 action under this paragraph. A revocation under this
21 paragraph shall become effective not later than 180
22 days after—

23 “(A) the date by which each such cancella-
24 tion of a registration has become effective, or

1 “(B) the date on which the use of the can-
2 celed pesticide becomes unlawful under the
3 terms of the cancellation, whichever is later.

4 “(3) SUSPENSION OF TOLERANCE OR EXEMP-
5 TION FOLLOWING SUSPENSION OF ASSOCIATED REG-
6 ISTRATIONS.—

7 “(A) SUSPENSION.—If the Administrator,
8 acting under the Federal Insecticide, Fungicide,
9 and Rodenticide Act, suspends the use of each
10 registered pesticide that contains a particular
11 pesticide chemical and that is labeled for use on
12 a particular food, due in whole or in part to die-
13 tary risks to humans posed by residues of that
14 pesticide chemical on that food, the Adminis-
15 trator shall suspend any tolerance or exemption
16 that allows the presence of the pesticide chemi-
17 cal, or any pesticide chemical residue that re-
18 sults from its use, in or on that food. The Ad-
19 ministrator shall use the procedures set forth in
20 subsection (e) in taking action under this para-
21 graph. A suspension under this paragraph shall
22 become effective not later than 60 days after
23 the date by which each such suspension of use
24 has become effective.

1 “(B) EFFECT OF SUSPENSION.—The sus-
2 pension of a tolerance or exemption under sub-
3 paragraph (A) shall be effective as long as the
4 use of each associated registration of a pesticide
5 is suspended under the Federal Insecticide,
6 Fungicide, and Rodenticide Act. While a sus-
7 pension of a tolerance or exemption is effective
8 the tolerance or exemption shall not be consid-
9 ered to be in effect. If the suspension of use of
10 the pesticide under that Act is terminated, leav-
11 ing the registration of the pesticide for such use
12 in effect under that Act, the Administrator
13 shall rescind any associated suspension of a tol-
14 erance or exemption.

15 “(4) TOLERANCES FOR UNAVOIDABLE RESI-
16 DUES.—In connection with action taken under para-
17 graph (2) or (3), or with respect to pesticides whose
18 registrations were canceled prior to the effective date
19 of this paragraph, if the Administrator determines
20 that a residue of the canceled or suspended pesticide
21 chemical will unavoidably persist in the environment
22 and thereby be present in or on a food, the Adminis-
23 trator may establish a tolerance for the pesticide
24 chemical residue at a level that permits such un-
25 avoidable residue to remain in such food. In estab-

1 lishing such a tolerance, the Administrator shall
2 take into account the factors set forth in subsection
3 (b)(2)(A)(iii) and shall use the procedures set forth
4 in subsection (e). The Administrator shall review
5 any such tolerance periodically and modify it as nec-
6 essary so that it allows only that level of the pes-
7 ticide chemical residue that is unavoidable.

8 “(5) PESTICIDE RESIDUES RESULTING FROM
9 LAWFUL APPLICATION OF PESTICIDE.—Notwith-
10 standing any other provision of this Act, if a toler-
11 ance or exemption for a pesticide chemical residue in
12 or on a food has been revoked, suspended, or modi-
13 fied under this section, an article of that food shall
14 not be deemed unsafe solely because of the presence
15 of such pesticide chemical residue in or on such food
16 if it is shown to the satisfaction of the Secretary
17 that—

18 “(A) the residue is present as the result of
19 an application or use of a pesticide at a time
20 and in a manner that was lawful under the
21 Federal Insecticide, Fungicide, and Rodenticide
22 Act; and

23 “(B) the residue does not exceed a level
24 that was authorized at the time of that applica-
25 tion or use to be present on the food under a

1 tolerance, exemption, food additive regulation,
2 or other sanction then in effect under this Act;
3 unless, in the case of any tolerance or exemption re-
4 voked, suspended, or modified under this subsection
5 or subsection (d) or (e), the Administrator has is-
6 sued a determination that consumption of the legally
7 treated food during the period of its likely availabil-
8 ity in commerce will pose an unreasonable dietary
9 risk.

10 “(k) FEES.—The Administrator shall by regulation
11 require the payment of such fees as will in the aggregate,
12 in the judgment of the Administrator, be sufficient over
13 a reasonable term to provide, equip, and maintain an ade-
14 quate service for the performance of the Administrator’s
15 functions under this section. Under the regulations, the
16 performance of the Administrator’s services or other func-
17 tions under this section, including—

18 “(1) the acceptance for filing of a petition sub-
19 mitted under subsection (d),

20 “(2) the promulgation of a regulation establish-
21 ing, modifying, or revoking a tolerance or establish-
22 ing or revoking an exemption from the requirement
23 of a tolerance under this section,

24 “(3) the acceptance for filing of objections
25 under subsection (d)(6), or

1 “(4) the certification and filing in court of a
2 transcript of the proceedings and the record under
3 subsection (d)(7),

4 may be conditioned upon the payment of such fees. The
5 regulations may further provide for waiver or refund of
6 fees in whole or in part when in the judgment of the Ad-
7 ministrators such a waiver or refund is equitable and not
8 contrary to the purposes of this subsection.

9 “(1) NATIONAL UNIFORMITY OF TOLERANCES.—

10 “(1) QUALIFYING PESTICIDE CHEMICAL RESI-
11 DUE.—For purposes of this subsection, the term
12 ‘qualifying pesticide chemical residue’ means a pes-
13 ticide chemical residue resulting from the use, in
14 production, processing, or storage of a food, of a
15 pesticide chemical that is an active ingredient and
16 that—

17 “(A) was first approved for such use in a
18 registration of a pesticide issued under section
19 3(e)(5) of the Federal Insecticide, Fungicide,
20 Rodenticide Act on or after April 25, 1985, on
21 the basis of data determined by the Adminis-
22 trator to meet all applicable requirements for
23 data prescribed by regulations in effect under
24 that Act on April 25, 1985; or

1 “(B) was approved for such use in a rereg-
2 istration eligibility determination issued under
3 section 4(g) of that Act on or after the date of
4 enactment of the Food Quality Protection Act
5 of 1993.

6 “(2) QUALIFYING FEDERAL DETERMINATION.—
7 For purposes of this subsection, the term ‘qualifying
8 Federal determination’ means—

9 “(A) a tolerance or exemption from the re-
10 quirement for a tolerance for a qualifying pes-
11 ticide chemical residue that was—

12 “(i) issued under this section after the
13 date of enactment of the Food Quality
14 Protection Act of 1993;

15 “(ii) issued (or, pursuant to sub-
16 section (h) or (i), deemed to have been is-
17 sued) under this section, and determined
18 by the Administrator to meet the standard
19 under subsection (b)(2) (in the case of a
20 tolerance) or (c)(2) (in the case of an ex-
21 emption); and

22 “(B) any statement, issued by the Sec-
23 retary, of the residue level below which enforce-
24 ment action will not be taken under this Act
25 with respect to any qualifying pesticide chemi-

1 cal residue, if the Secretary finds that such pes-
2 ticide chemical residue level permitted by such
3 statement during the period to which such
4 statement applies protects human health.

5 “(3) LIMITATION.—The Administrator may
6 make the determination described in paragraph
7 (2)(A)(ii) only by issuing a rule in accordance with
8 the procedure set forth in subsection (d) or (e) and
9 only if the Administrator issues a proposed rule and
10 allows a period of not less than 30 days for comment
11 on the proposed rule. Any such rule shall be
12 reviewable in accordance with subsections (d)(6) and
13 (d)(7).

14 “(4) STATE AUTHORITY.—Except as provided
15 in paragraph (5), no State or political subdivision
16 may establish or enforce any regulatory limit on a
17 qualifying pesticide chemical residue in or on any
18 food if a qualifying Federal determination applies to
19 the presence of such pesticide chemical residue in or
20 on such food, unless such State regulatory limit is
21 identical to such qualifying Federal determination. A
22 State or political subdivision shall be deemed to es-
23 tablish or enforce a regulatory limit on a pesticide
24 chemical residue in or on food if it purports to pro-
25 hibit or penalize the production, processing, ship-

1 ping, or other handling of a food because it contains
2 a pesticide residue (in excess of a prescribed limit),
3 or if it purports to require that a food containing a
4 pesticide residue be the subject of a warning or
5 other statement relating to the presence of the pes-
6 ticide residue in the food.

7 “(5) PETITION PROCEDURE.—

8 “(A) Any State may petition the Adminis-
9 trator for authorization to establish in such
10 State a regulatory limit on a qualifying pes-
11 ticide chemical residue in or on any food that
12 is not identical to the qualifying Federal deter-
13 mination applicable to such qualifying pesticide
14 chemical residue.

15 “(B) Any petition under subparagraph (A)
16 shall—

17 “(i) satisfy any requirements pre-
18 scribed, by rule, by the Administrator; and

19 “(ii) be supported by scientific data
20 about the pesticide chemical residue that is
21 the subject of the petition or about chemi-
22 cally related pesticide chemical residues,
23 data on the consumption within such State
24 of food bearing the pesticide chemical resi-
25 due, and data on exposure of humans with-

1 in such State to the pesticide chemical res-
2 idue.

3 “(C) Subject to paragraph (6), the Admin-
4 istrator may, by order, grant the authorization
5 described in subparagraph (A) if the Adminis-
6 trator determines that the proposed State regu-
7 latory limit—

8 “(i) is justified by compelling local
9 conditions;

10 “(ii) would not unduly burden inter-
11 state commerce; and

12 “(iii) would not cause any food to be
13 in violation of Federal law.

14 “(D) In lieu of any action authorized
15 under subparagraph (C), the Administrator
16 may treat a petition under this paragraph as a
17 petition under subsection (d) to revoke or mod-
18 ify a tolerance or to revoke an exemption. If the
19 Administrator determines to treat a petition
20 under this paragraph as a petition under sub-
21 section (d), the Administrator shall thereafter
22 act on the petition pursuant to subsection (d).

23 “(E) Any order of the Administrator
24 granting or denying the authorization described
25 in subparagraph (A) shall be subject to review

1 in the manner described in subsections (d)(6)
2 and (d)(7).

3 “(6) RESIDUES FROM LAWFUL APPLICATION.—

4 No State or political subdivision may enforce any
5 regulatory limit on the level of a pesticide chemical
6 residue that may appear in or on any food if, at the
7 time of the application of the pesticide that resulted
8 in such residue, the sale of such food with such resi-
9 due level was lawful under this Act and under the
10 law of such State, unless the State demonstrates
11 that consumption of the food containing such pes-
12 ticide residue level during the period of the food’s
13 likely availability in the State will pose an unreason-
14 able dietary risk to the health of persons within such
15 State.”.

16 **SEC. 306. AUTHORIZATION FOR INCREASE MONITORING.**

17 There is authorized to be appropriated an additional
18 \$12,000,000 for increased monitoring by the Secretary of
19 Health and Human Services of pesticide residues in im-
20 ported and domestic food.

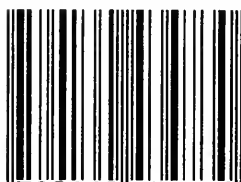
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